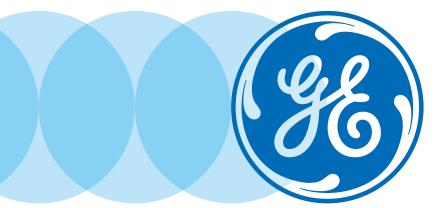
## **CARESCAPE R860** Participant Guide

Software Revision 10



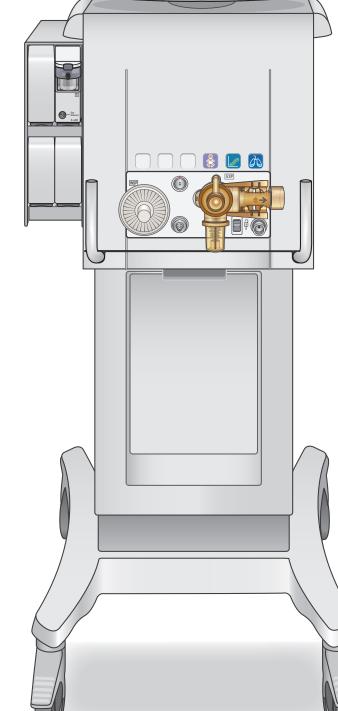


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 Proof Pressure

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Tidal Volume respiratory Rest

62 0

**Global Customer Education** 

# CARESCAPE R860

### **Software Revision 10** Participant Guide

**Global Customer Education** 

## Customer Support Center: 800-345-2700

#### Notice

Configurations available for this product depend on local market and standards requirements. Illustrations in this material may not represent all configurations of the product. This material does not cover the operation of every accessory.

This material is intended for educational purposes only. This material does not establish specifications, operating procedures or maintenance methods for any of the products referenced. Always refer to the official written materials (labeling) provided with the product for specifications, operating procedures and maintenance requirements.

This material may include clinical concepts and definitions. No diagnostic statements are inferred or included in this material. All clinical diagnosis should be made by a trained physician or clinician. All patient names or other protected health information or data contained in any image within this material is fictitious. Any similarity to actual persons is coincidental.



**Note!** This participant guide is not intended to replace the User's Reference Manuals that you received with the machine. Please refer to the disclaimer notice at the end of this participant guide for more information.

This course is intended for CARESCAPE R860 software level 10. The material contained in this course is intended for educational purposes only. Always refer to the official written materials provided with the CARESCAPE R860 for specifications, operating procedures, and maintenance requirements.

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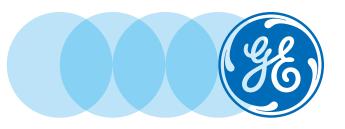
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## 1 Welcome



We would like to take a moment to thank you for choosing GE Healthcare for your ventilator needs. Our goal now is to provide you with the best training service available while continuing to support you as you use our products in your workplace

## **Class Description**

This course is designed to give Participants the information and product knowledge needed to proficiently operate the CARESCAPE R860 ventilator.

## Participant Learning Objectives

Specific learning objectives will be listed for each section at the beginning of the section. Overall learning objectives include:

- Describe the main components of the system
- Connect and attach the proper components for use
- Navitate the system and change a setting or view
- Power the system on and off
- Run a system check
- Start patient ventilation
- Manage alarms
- Describe the available ventilation modes
- Perform the available procedures
- Configure waveform and spirometry settings
- View the available trends
- Perform proper cleaning and maintenance procedures

## 2 Overview



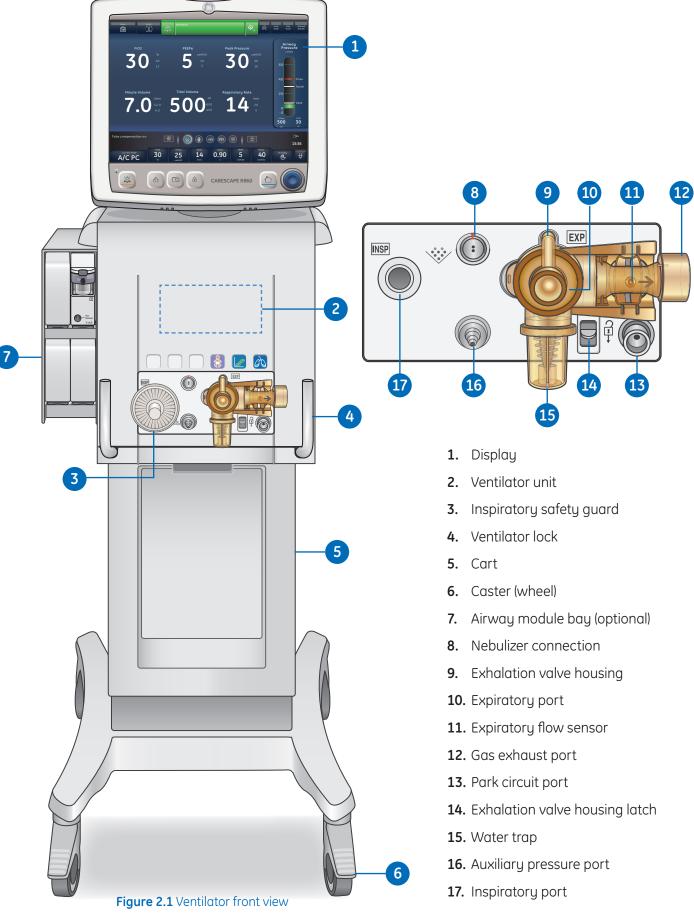
## **Overview Objectives**

#### After completing this section, the participant will be able to:

- Describe the main components of the system
- Connect and Remove the Exhalation Valve Housing
- Connect the Gas Supplies
- Connect the Exhalation Valve Heater
- Connect the Accessory Rail
- Attach the Rail Adapter to the Accessory Rail
- Attach System Accessories
- Connect the Breathing Circuit
- Connect the Humidifier
- Connect the Nebulizer
- Connect the Airway Module and Module Bay
- Connect the Pedi-lite(+) and D-lite(+) Sensors



## Ventilator Front



## Ventilator Back

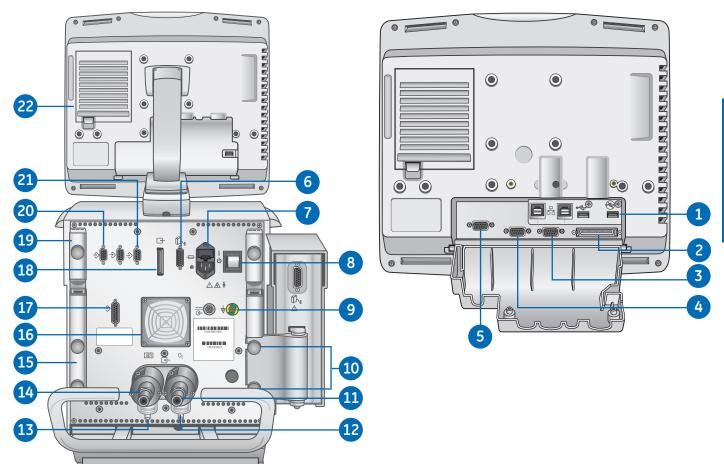


Figure 2.2 Ventilator back view

- 1. USB connection (Service connection)
- 2. Display Unit connection
- 3. VGA (not for clinical use)
- 4. Port 6 (RS232 Serial communication port)
- 5. Port 5 (RS232 Serial communication port)
- 6. Module bay connection
- 7. Main power inlet and fuse holder
- 8. Power switch
- 9. Equipotential stud
- **10.** Module bay mounting thumbscrews
- **11.** Oxygen supply connection (pipeline)
- 12. O<sub>2</sub> high-pressure inlet filter (optional)
- 13. Air high-pressure inlet filter
- 14. Air supply connection (pipeline)

- 15. Retaining channel
- 16. Ventilator unit fan filter
- 17. Port 4 (Nurse call)
- 18. Display Unit connection
- 19. Patient circuit support arm
- 20. Port 1 (neonatal flow sensor connection)
- 21. Port 3 (exhalation valve heater connection)
- 22. Display unit fan filter

## **Connecting Power**

The power cord is connected on the back of the ventilator as shown.

The input power is less than 200 VA.

- 1. Connect the power cord to the AC power outlet.
- 2. Press the power switch to turn on the ventilator.
- 3. Wait approximately 30 seconds to allow the system to warm up.

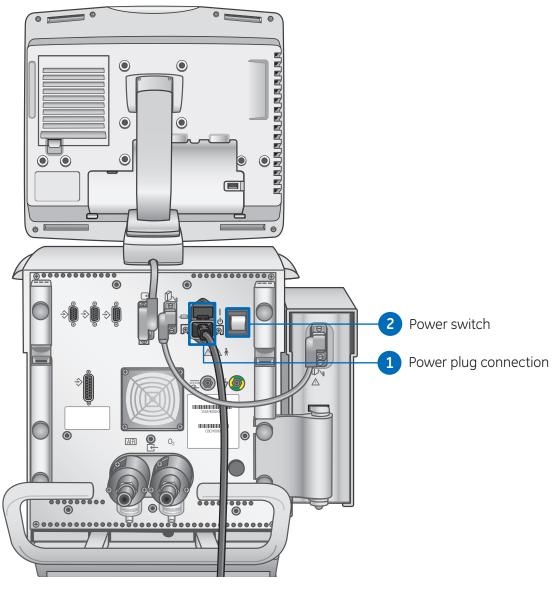


Figure 2.3 Power connection and switch

## Connecting and Removing the Exhalation Valve Housing

The exhalation valve housing contains the expiratory flow sensor and water trap.

- 1. To attach the housing, place the tab of the housing into the groove
- 2. Push the housing into position.
  - Listen for audible click and then gently pull on the housing to make sure it is securely latched.
- **3.** To remove the housing, press down on the latch to release the exhalation valve housing and then pull the housing from the ventilator.
- 4. Unscrew the water trap to remove from the housing to empty or clean.

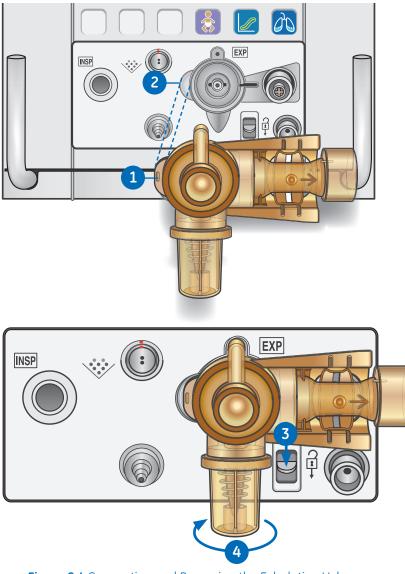


Figure 2.4 Connecting and Removing the Exhalation Valve

### **Connecting Gas Supplies**

The  $O_2$  and air supply connections are located on the back of the ventilator. The air supply connection is on the left side and the  $O_2$  supply connection is on the right side as labeled on the ventilator. The ventilator comes with a standard air pipeline inlet assembly which includes a filter bowl, o-ring, and filter element. The  $O_2$  pipeline inlet filter assembly can be ordered.

- 1. Connect the air supply connection to the back of the ventilator and tighten.
- 2. Connect the O<sub>2</sub> supply connection to the back of the ventilator and tighten.

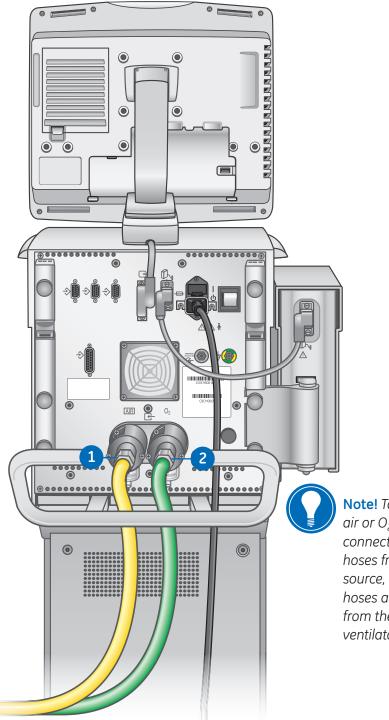


Figure 2.5 Connecting the Gas Supply

**Note!** To disconnect the air or  $O_2$  gas supply connections: unscrew the hoses from the gas supply source, then unscrew the hoses and remove them from the back of the ventilator.

### Connecting the Exhalation Valve Heater

Use the exhalation valve heater to prevent moisture from condensing in the expiratory flow sensor when a humidifier is used.



**Note!** Port 3 must only be used for connecting the exhalation valve heater cable.

- 1. Attach and tighten the cable to Port 3 on the back of the ventilator.
- 2. Thread the cable through the rear channel to the front of the ventilator.
- 3. Angle the cover over the exhalation valve housing and gently press into place.
- **4.** Align and match the red dots from the exhalation valve heater cable to the power cable and snap together. Connecting the cable will power on the exhalation valve heater.



**Note!** To disconnect and remove the exhalation valve heater, follow instructions in reverse order.

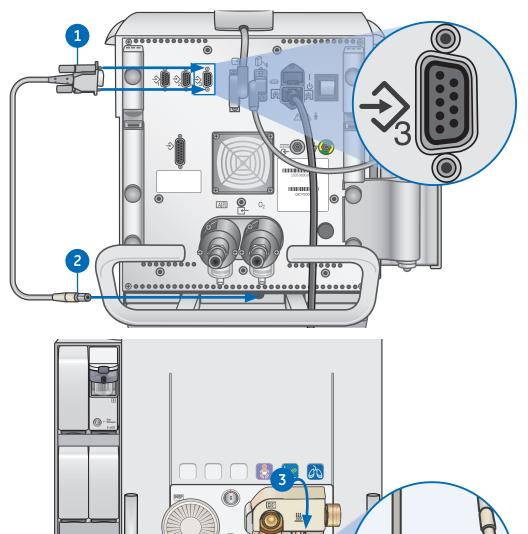
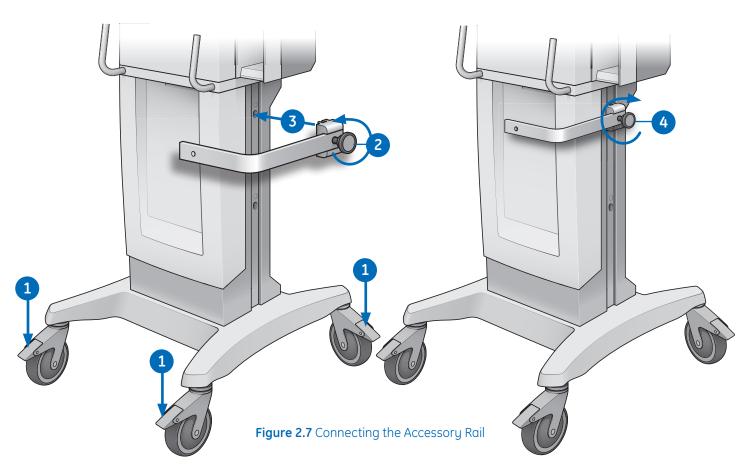


Figure 2.6 Connecting the Exhalation Valve Heater

LIGO OL

## Connecting the Accessory Rail

- 1. Lock the casters on the ventilator cart.
- 2. Loosen the rail mount thumbscrew.
  - The wedge assembly on the rail is spring-loaded to allow rail installation into the dove-tail of the cart.
- **3.** Use the leading edge of the wedge assembly to insert the rail into the dovetail located on either side of the ventilator cart.
- 4. Tighten the thumbscrew to secure the rail at the desired height.
  - The accessory rail position can be adjusted by loosening the thumbscrew, sliding the accessory rail to the desired location, and then tightening the thumbscrew.



## Attaching the Rail Adapter to the Accessory Rail

- 1. Loosen the thumbscrew on the rail adapter and attach it to the rail.
- 2. Slide the rail adapter to the desired location and tighten the thumbscrew to secure the adapter to the rail.
  - The rail adapter position can be adjusted by loosening the thumbscrew, sliding the rail adapter to the desired location, and then tightening the thumbscrew.
- 3. When the adapter is at the desired location, tighten the thumbscrew.
  - Make sure the rail adapter is positioned correctly (thumbscrew down).

**Note!** Maximum capacity for the accessory rail is 10 kg.

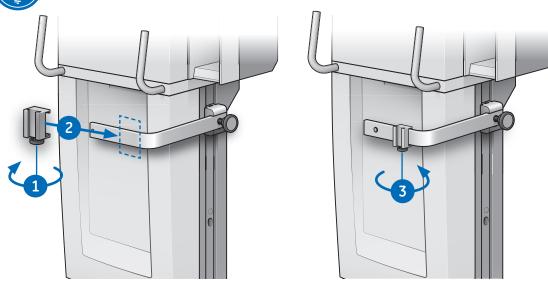


Figure 2.8 Connecting the Rail Adapter

### Attaching System Accessories

The accessory rail and rail adapter are used to mount systems accessories to the cart.



Note! Maximum capacity for the accessory rail is 10 kg.

Add accessories to the accessory rail adapter.

- **1.** Make sure the adapter is positioned correctly (thumbscrews down).
- 2. Slide accessories into the adapter.

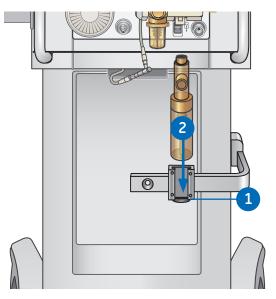


Figure 2.9 Attaching an Accessory

## Connecting the Breathing Circuit

- Check all connections to the breathing circuit to make sure that there are no unintended connections made to other equipment, especially equipment that delivers fluids, as the patient could be harmed.
- The inspiratory safety guard is required to connect the breathing circuits to the ventilator. The inspiratory safety guard must be used at all times during ventilation.



**Note!** Consult your hospital guidelines for proper use of expiratory filters in conjunction with heated humidifiers.

## Connecting the Humidifier

The ventilator is designed to work with active humidification. GE Healthcare recommends the use of the Fisher & Paykel MR850 humidifier (refer to humidifier instructions for detailed information on humidifier connections and use).

When adding attachments or other components to the ventilator, the pressure gradient across the breathing circuit may change.

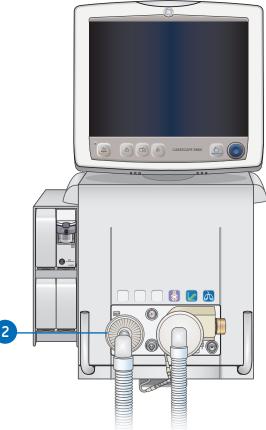


Figure 2.10 Breathing Circuit Connection

Note! N

**Note!** Never position any filter in the inspiratory limb downstream of a humidifier.

- 1. Slide the humidifier heater onto the accessory rail (do not plug in).
- 2. Press down on the light blue lever of the humidifier and slide the water chamber into the humidifier heater. Release the light blue part of the humidifier heater.
- **3.** Unwrap the water feed line from the humidifier water chamber and puncture the water reservoir. The water reservoir should be elevated above the humidifier at all times and water should flow down into the humidifier.
- **4.** Use the short blue circuit tubing from the humidifier circuit pack and connect one end to the inspiratory safety guard and the other end to the appropriate port on the humidifier chamber.
- Connect the longer piece of blue circuit tubing to the remaining port on the humidifier. Connect the end of the white circuit tubing to the expiratory port or expiratory filter (if used).

- 6. Connect the heater wire to the humidifier heater, then connect the two leads to the ends of the patient circuit (the shorter lead to the blue tube).
- 7. Connect the temperature probe to the humidifier heater, connecting the keyed lead to the end of the blue tube of the patient circuit and the other to the patient wye for adult (near the patient wye on the blue tube for pediatric/neonatal).



**Note!** The thermal operating temperature of the humidifier is 18-26° C according to the manufacturer.

2

- 8. Turn on the ventilator and perform the System Check. See **System Check** in the Operation section of the user's reference manual for more information.
- 9. If the System Check passes, plug in the humidifier and attach the exhalation valve heater. See *Connecting the exhalation valve heater* in the user's reference manual.



**Note!** To disconnect, follow the instructions in reverse order.

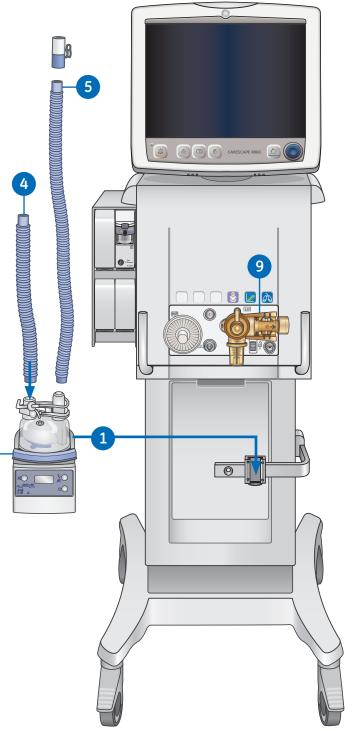


Figure 2.11 Attaching the Humidifier

#### CARESCAPE R860 Participant Guide

#### Patient Circuit Connection with Humidifier Components

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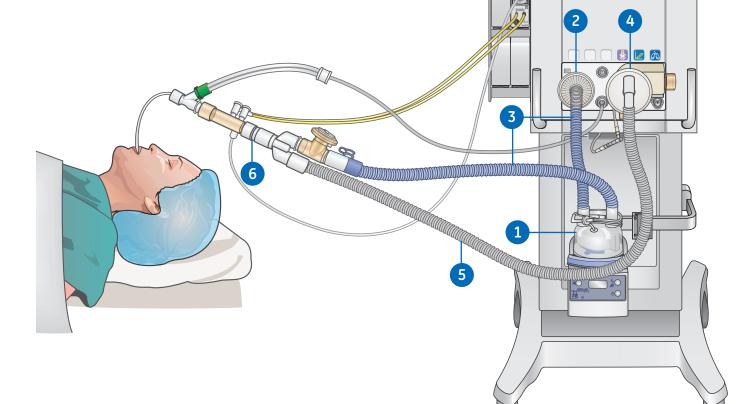
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Figure 2.12 Patient Circuit with Humidifier

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- 1. Humidifier (Fisher & Paykel)
- 2. Inspiratory safety guard
- 3. Inspiratory limb to and from humidifier to patient wye
- 4. Expiratory port/expiratory filter if used
- 5. Expiratory limb
- 6. Spacer (5 ml minimum)



## Connecting the Nebulizer

The Aerogen Professional Nebulizer System is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions and suspensions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

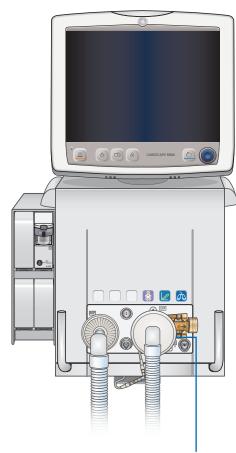
The CARESCAPE R860 supports the Aerogen Professional Nebulizer System (Aerogen Pro and Aerogen Solo). Both nebulizer devices operate in-line using the ventilator nebulizer menu and nebulizer cable. The Aerogen Pro and Aerogen Solo are purchasable parts, see "Parts and accessories" section in the user's reference manual for ordering information.

The Aerogen Pro and Aerogen Solo (disposable) may be used with neonatal, pediatric, and adult patients in acute and subacute care environments. Both nebulizer models operate without changing the patient ventilator parameters and can be refilled without interrupting ventilation.

The nebulizers may be used with a neonatal, pediatric, or adult breathing circuit. The T-adapter for the nebulizer is specific to the breathing circuit type.



**Note!** It is strongly recommended to use an expiratory filter when a nebulizer is used to help protect the expiratory flow sensor.



```
Figure 2.13 Expiratory Filter
```

#### **Disposable Nebulizer**

The Aerogen® Solo nebulizer is a disposable nebulizer for single patient use. The Aerogen Solo can be used with neonatal, pediatric, and adult patients. The Solo nebulizer operates in-line like the Aerogen Pro, utilizing the ventilator nebulizer menu and nebulizer cable. See **Nebulizer** *treatment* in the **Procedures** section of the user's reference manual for additional information.

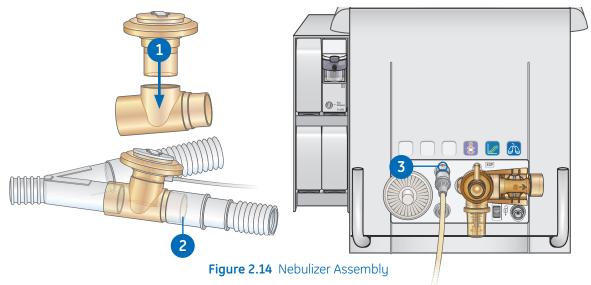


**Note!** The Aerogen Solo and accessories are disposable and should not be cleaned or reused after single patient use.

#### Assembling the Nebulizer

**Warning!** Always maintain the nebulizer in a vertical orientation while it is in the patient circuit. This orientation helps prevent patient secretions and condensation from contaminating the aerosol generator of the nebulizer and ensures proper nebulization.

- 1. Connect the nebulizer to the T-adapter by pushing the nebulizer firmly onto the adapter.
- **2.** Connect the nebulizer and T-adapter into the inspiratory limb of the breathing circuit before the patient wye.
- 3. Attach the nebulizer cable to the nebulizer connection as shown, matching the red dots.
- **4.** Complete a System Check prior to use on a patient. *See System Check* in the Operation section of the user's reference manual for additional information.
- **5.** Follow the *Nebulizer treatment* procedure in the Procedures section in the user's reference manual.

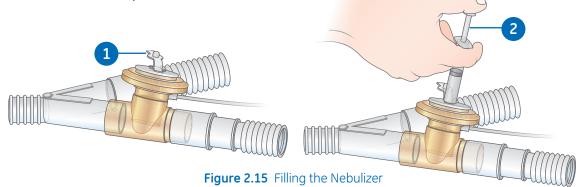


#### **Filling the Nebulizer**

**Caution!** To help avoid damage to the nebulizer, do not use a syringe with a needle. Do not push or apply undue pressure to the domed aperture plate in the center of the nebulizer.

The maximum capacity of the Pro nebulizer unit is 10 ml. The maximum capacity of the Solo nebulizer is 6 ml. Do not fill the nebulizer beyond the maximum fill indication point. The underside of the filler cap represents the maximum fill indication point.

- 1. Open the filler cap tab on the nebulizer.
- 2. Use a prefilled nebule or syringe to inject the medication into the filler port.
- **3.** Close the filler cap tab.



2.14

#### Disassembling the Nebulizer

The nebulizer and T-adapter may remain in the patient circuit when not in use. The nebulizer may be removed from the T-adapter and replaced with a plug to avoid leaks.

- **1.** To remove the nebulizer cable from the nebulizer, grasp it close to the ventilator and pull straight out.
- 2. Remove the nebulizer and T-adapter from the inspiratory limb of the patient breathing circuit. Reconnect the circuit.
- **3.** Clean and sterilize the Pro nebulizer and T-adapter as described in the *Cleaning and Maintenance* section of the user's reference manual.

#### **Functional Test**

Perform a functional test of Aerogen nebulizers prior to first use, after each sterilization, before each patient use, or at any time to verify proper operation.

Inspect all parts before use, and do not use if any parts are missing, cracked or damaged.



**Note!** The time and approximate volume of nebulized medication are shown in the table. The calculated volume is based on an average nebulization rate of 0.38 ml/min, but the actual nebulization rate of each individual nebulizer cannot be guaranteed and may vary.

- **1.** Visually inspect each part of the device for cracks or damage and replace if defects are visible.
- 2. Pour 1-5 ml of normal saline (0.9%) into the nebulizer unit.
- **3.** Connect the nebulizer. Follow the instructions in *Connecting the nebulizer* in the Setup and Connections section of the user's reference manual.
- 4. Select Menu > Nebulizer > Aerogen.
- 5. Select *Time >* 16 *minutes*.

The time and approximate volume of nebulized medication are shown in the table below.

Selecting **Continuous** will deliver nebulized medication until medication delivery is stopped or runs out.

Time (min)	7	8	11	16	21	26	32
Volume (ml)	2.5	3.0	4.0	6.0	8.0	10.0	12.0

- 6. Select *Start* and verify that aerosol is visible.
- 7. Select *Stop* to end the nebulizer treatment and verify that aerosol is not visible.
- 8. Discard any remaining liquid before patient use.

## Airway Modules

Airway modules measure and monitor gases delivered to and from the patient.

#### Airway modules have:

- Nondispersive infrared technology to measure CO<sub>2</sub>, N<sub>2</sub>O, and anesthetic agents.
- Paramagnetic technology to measure O<sub>2</sub>.
- Differential pressure detection to measure spirometry inputs from the D-lite(+) or Pedi-lite(+) sensor.
- D-fend water trapping system to prevent moisture from entering the measurement chamber.

Some measurements are made by internal sensors in either the ventilator or the airway module. The Airway Module (Patient) data icon is shown below the airway pressure bar when selected as the data source.





Figure 2.17 Airway Module Patient Data Icon

When Airway Module is selected as the data source, the data source icon will not be updated until the module is able to provide information. This may take 2 to 5 minutes when a module is first installed into the module bay. Only information available from the installed airway module will be displayed on the ventilator; all other data will be from the ventilator.

For example, if a module capable of measuring CO2 and O2 only is installed, CO2 and O2 data displayed will be from the module; all other data will be from the ventilator. If Airway Module is selected as the data source and the airway module is removed from the module bay, the data source icon will show Ventilator as the data source. Monitoring that is critical to patient safety comes from both the ventilator and the airway module when the data source is Airway Module. In some conditions, alarms might be triggered by the ventilator sensors, while the measurements shown are from the airway module sensors.



**Note!** The airway module spirometry keys do not function when it is installed in the ventilator. These functions are available through the ventilator.

**Important!** The ventilator is not intended for use with anesthetic agents and does not measure or show anesthetic agent data.

#### Compatible airway modules

• E-sCAiO

The following airway modules are compatible with the ventilator:

- E-miniC E-sCO
- E-CO E-sCOV
- E-COV E-sCOVX
- E-COVX
- E-CAIO E-sCAIOV
- E-CAIOV E-sCAIOVX
- E-CAiOVX



Figure 2.18 Examples of E-series Modules

The letters in the airway module model number correspond to its model and capabilities.

- **E** = plug-in gas module
- **s** = single width airway module
- $\mathbf{C} = CO_2$  detection
- A = anesthetic agent detection (not supported)
- i = anesthetic agent identification (not supported)
- $\mathbf{O}$  = patient  $O_2$  detection
- V = patient spirometry
- **X** = metabolics

#### **E-series Airway Module Components**

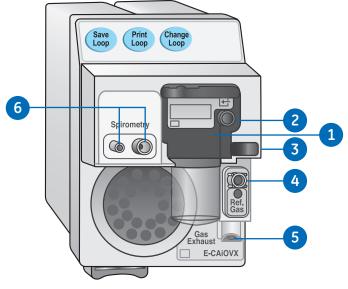


Figure 2.19 E-series Airway Modules

- 1. D-fend water trap
- 2. Gas sampling line connector on the water trap
- 3. Water trap latch



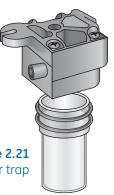
Figure 2.20 CARESCAPE Airway Modules

- 4. Reference gas inlet
- 5. Gas sampling outlet
- 6. Connectors for patient spirometry

#### D-fend Water Trap

The airway module includes a single use D-fend water trap. The water trap has a hydrophobic membrane that prevents condensed water and secretions from entering the airway module measuring chamber. The condensed water and secretions are collected in a washable container.

> **Figure 2.21** D-Fend Water trap



#### Connecting the Airway Module and Module Bay

The airway module bay may be attached on either side of the ventilator.



**Note!** Do not place the airway module in the lower slot when the airway module bay is on the right side of the system. Exhaust from the gas exhaust port will adversely affect accuracy of airway module  $CO_2$  and  $O_2$  measurements.

Install only one airway module into the airway module bay. The system does not support the use of multiple airway modules.

Only install single width airway modules (E-miniC and CARESCAPE respiratory modules) in the upper right slot of the airway module bay. The upper left slot of the module bay does not support communication between the module and the system.

- 1. Lock the ventilator cart wheels.
- 2. Connect one end of the cable to the airway module bay connection on the back of the ventilator, and tighten the screws.
- **3.** To attach the module bay, loosen the thumbscrews on the desired side of the ventilator.
- **4.** Slide the airway module bay behind the thumbscrews and tighten.
- 5. Connect the end of the cable to the airway module bay connection, and tighten the screws.

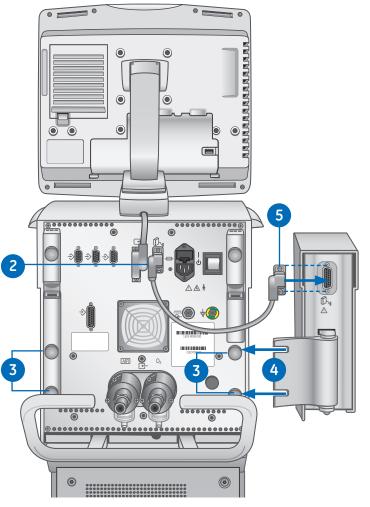
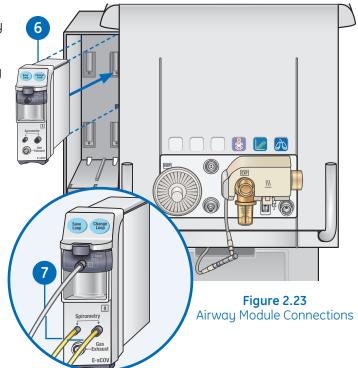


Figure 2.22 Module Bay Back Connections

- 6. Slide the airway module into the upper portion of the airway module bay.
- 7. Attach the tubing to the airway module.

#### To Disconnect the Airway Module Bay:

- 8. Remove the airway module from the airway module bay.
- **9.** Remove the cable from the airway module bay from the back of the ventilator.
- **10.** Loosen the airway module bay thumbscrews and remove the airway module bay.



## Connecting the Pedi-lite(+) and D-lite(+) Sensors



**Note!** Use the Pedi-lite(+) sensor for patients with tidal volumes up to, and including 200 ml.

Use the D-lite(+) sensor for patients with tidal volumes greater than 200 ml.

To ensure patient safety, make sure that the gas sampling connectors are connected as described in these instructions and are not interchanged with connectors on other equipment.

The D-lite(+) and Pedi-lite(+) sensors have a port to provide gas samples to the airway module. Both sensors are available as reusable (yellow) or disposable (clear).

Airway pressures are measured between the patient wye and the patient airway with a D-lite(+) or Pedi-lite(+) sensor. The sensors have a two-sided Pitot tube used to measure pressure. The pressure difference across a flow restrictor is used to calculate flow. From the flow, inspiratory volume and expiratory volume are calculated.

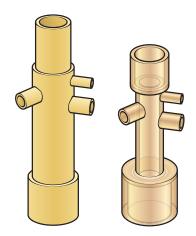
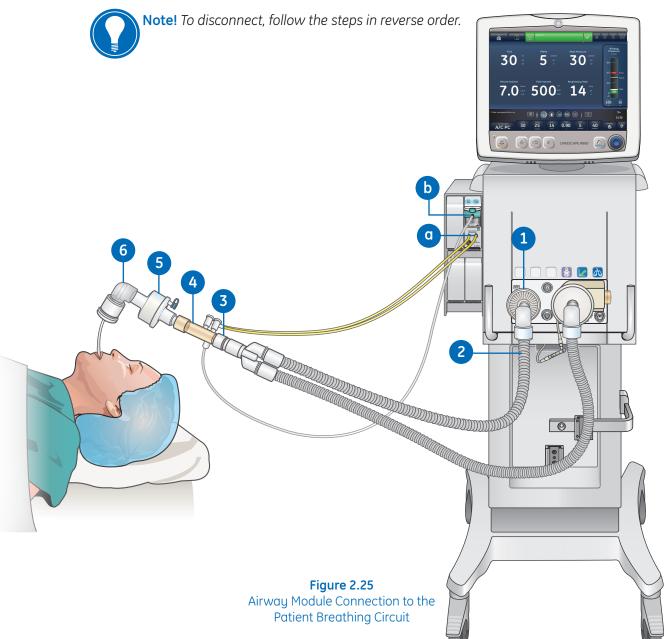


Figure 2.24 Dlite(+) Sensors or Pedi-lite(+)

#### Connecting the Pedi-lite(+) or Dlite(+) Sensor

- **1.** Connect the inspiratory safety guard to the inspiratory port.
- 2. Connect the inspiratory limb of the patient circuit to the inspiratory safety guard.
- 3. Connect a 5 ml (minimum) spacer at the circuit wye.
- **4.** Connect the Pedi-lite(+) or D-lite(+) sensor to the patient circuit and make the following connections:
  - **a.** Connect the spirometry tubes from the Pedi-lite(+) or Dlite(+) sensor to the airway module.
  - **b.** Connect the gas sampling line from the Pedi-lite(+) or Dlite(+) sensor to the D-fend water trap on the airway module.
- 5. Optionally, connect the heat and moisture exchange with filter (HMEF).
- **6.** Connect an elbow after the HMEF (if used), or after a D-lite or Pedi-lite sensor (if used and an HMEF is not used).



# 3 Navigation



## Navigation Objectives

#### After completing this section, the participant will be able to:

- Describe the main components on the display
- Navigate Active Alarms
- Place the system in Standby
- Access and navigate the Main Menu
- Change a Setting
- Navigate the User Interface
- Access the Present/Patient Status Workspace and Views
- Access the Basic Waveform View
- Access the Advanced Waveform View
- Access the Past/Historical Trends Workspace and Views
- Access the Future/Clinical Decision Support Workspace and Views
- Access the Snapshot Trends View



## Ventilator Display

#### Overview

The 15-inch touchscreen display provides audible and visual alarms, integrated key pad, and a Trim Knob control. To select menu options or settings, touch only one touch point at a time to make sure the correct selection is made. Touch the setting or press the Trim Knob to confirm settings.

The touchscreen allows swipe gestures to move from one workspace to another workspace.

Do not use pencils, pens, or other objects to activate the touchscreen. The touchscreen will not function properly if tape or paper is stuck to the display surface.

- **1.** Alarm light: The integrated alarm light provides a visual alarm when an alarm condition occurs. The alarm light also provides a visual indicator when Audio Pause is active and alarm audio is silenced.
- **2. Trim knob control:** Turn the Trim Knob clockwise or counterclockwise to change a setting. Press the Trim Knob to confirm a setting.
- **3.** Hard keys (key pad): Press the Audio Pause, Increase O2, Snapshot, Lock/Unlock, or Home hard keys to access the associated features.
  - Audio Pause: Press to silence alarms for 120 seconds.
- **4. LED indicator:** The green LED illuminates when the ventilator is connected to the main power supply. The internal battery is charging when the LED is lit.

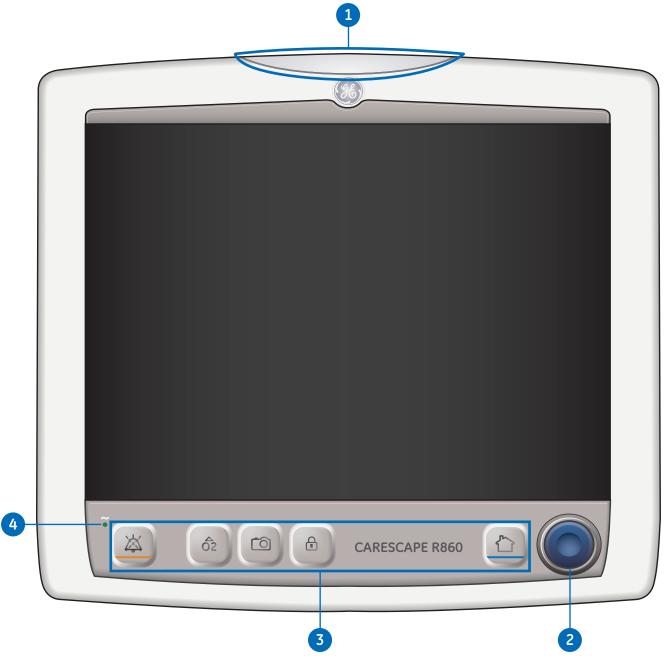


Figure 3.1 Display controls and indicators

#### **Display User Interface**

The user interface incorporates the Menu, Current Patient information, alarm management, and Favorites procedures at the top of the display. The patient status (airway pressure bar) and workspace/monitoring area are located in the middle of the display. The navigation bar, message areas, battery status, standby, and quick keys are located at the bottom of the display.

- 1. Favorites: Provides short-cuts for up to four procedures (as selected by the user). Use to select specific procedures such as Increase O<sub>2</sub>, Inspiratory Hold, Expiratory Hold, and Manual Breath.
- 2. Patient status: The airway pressure bar shows a dynamic view of the patient airway pressure, Pmax, Ppeak, PEEP, FiO<sub>2</sub>, and VTexp. Use the tab on the pressure bar to collapse (hide) from view when available.
- **3.** Data Source: Some measurements are made by internal sensors in either the ventilator or the airway module. The Airway Module (Patient) data icon is shown when selected as the data source. The Ventilator data icon is shown when it is selected as the data source.
- **4. Main power:** Indicates whether the ventilator is connected to the main power supply or is running on battery. Also shows battery status when running on battery.
- 5. Additional Information: Shows current time and additional setting information.
- 6. **Standby:** Select the Standby quick key to go into Standby (pause/stop ventilation). See *Standby* in the *Operation* section of the URM.
- 7. Quick Keys: Select to change the corresponding ventilator setting. Turn the Trim Knob to make a change. Select the quick key or press the Trim Knob to activate the change. When a quick key setting is selected, a Trim Knob visual cue indicates the change may be made by turning the Trim Knob and pressing to confirm the setting.
- 8. Navigation: Select an icon to open the corresponding view. See *Navigating the user interface* in the URM for detailed information.
- **9.** Current Mode and Mode Settings: Shows the active ventilation mode. Select to access ventilation modes and change mode settings.
- **10. General Messages:** Shows notices, procedure status, and system status information to the user. See *General messages* in the *Alarms and troubleshooting* section of the URM.
- **11.** Monitoring: This area is used to view waveforms, measured data, and settings.
- **12. Menu:** Select to quickly access options such as: System menu, Procedures, Lung Mechanics, Suction, and Nebulizer.
- **13. Current Patient menu:** Select to enter the Current Patient menu. This menu allows entry of the patient ID using an alpha-numeric keyboard. Entered values for patient gender, height, and weight are used to calculate BSA (body surface area), and IBW (ideal body weight). This menu also allows the selection of tube type and diameter.
- 14. Alarm management: Select to view alarms, alarm history, alarm setup, and alarm help.



Figure 3.2 Display user interface components

3 Navigation

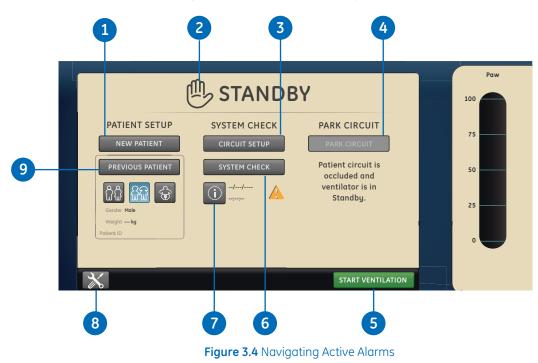
#### **Navigating Active Alarms**

When an alarm occurs for measured data, the number and alarm limits are shown with a border around them. The color of the border shows the priority of the alarm. Select within the border of the active alarm to open the *Alarm Setup* menu. Select the alarm limit that needs adjustment, and then use the Trim Knob to adjust the setting and confirm changes.



#### Standby

Standby is displayed upon system startup or when the **Standby** quick key is selected. When the system is in Standby, the **Standby** quick key and the patient status (airway pressure) bar are colored tan. A "Standby" message is displayed in the navigation bar when in the Present/ Patient Status workspace. Standby is used to stop ventilation to the patient, select a **New** or **Previous** patient, perform a **System Check**, and **Park/Unpark** the patient circuit.



- 1. New Patient: Select New Patient to enter patient information.
- **2. Standby:** When Standby (hand icon) is selected the Standby menu displays. If the Patient detected alarm occurs, the Standby menu automatically displays.
- **3. Circuit Setup:** Select Circuit Setup to select HME or Humidifier for adult and pediatric patient types.
- 4. **Park/Unpark Circuit:** When the circuit is parked a message displays: Patient circuit is occluded and ventilator is in Standby.
- 5. Start Ventilation: Select to start patient ventilation.
- 6. System Check: Select System Check to perform a ventilator system check.
- **7. Information:** Select to access information regarding the system check status and troubleshooting.
- **8. Setup:** Select to access the Configuration (Super User) and Service menus. A password is required to enter these menus. Contact a training representative to obtain the password.
- **9. Previous Patient/Current Patient:** Select Previous Patient to use the previous patient's ventilator settings and patient information. Select Current Patient to open the Current Patient menu and use the current patient's ventilator settings and patient information.

#### Main Menu

Select **Menu** to quickly access ventilator features and options. The main Menu accesses the *System menu, Procedures, Lung Mechanics, Nebulizer* and *Suction* option.



#### Figure 3.5 Navigating Active Alarms

- 1. System: Use the System menu to access data source, module type and version, calibrations (Paux Zero and Purge Flow), and display brightness. The System menu shows the software version, running hours, altitude, O<sub>2</sub> supply pressure, air supply pressure, and battery status.
- 2. **Procedures:** Use the Procedures menu to access the Assign Favorites menu and the following procedures: Manual Breath, Increase O<sub>2</sub>, Inspiratory Hold, Expiratory Hold, and Auto PEEP.
- **3.** Lung Mechanics: Use the Lung Mechanics menu to access the Assign Favorites menu and the following procedures: P0.1, Negative Inspiratory Force (NIF), and Vital Capacity.
- **4. Nebulizer:** Use the Nebulizer menu to access the Aerogen and Pneumatic Nebulizer procedures.
- **5. Suction:** Use the Suction menu to access the Assign Favorites menu and the Suction procedure.

# Changing a Setting

The Trim Knob graphic is used to indicate that the use of the Trim Knob is necessary to change or confirm a setting.



Figure 3.6 Trim Knob Graphic

- **1.** Touch the setting.
- 2. Change the value by turning the Trim Knob or selecting a menu item.
- **3.** Touch the setting or push the Trim Knob to confirm the setting.

To cancel or back out of a setting change, select **X** in the lower right corner of the menu (when available), touch outside of the setting twice, select the **Home** hard key, or wait for the selection to time out.

For example, ventilation and alarm setting changes can be cleared by selecting the *Home* hard key prior to confirming a setting.



Figure 3.7 Home Hard Key

### Navigating the User Interface

The ventilator user interface uses three different workspaces: Past/Historical trends, Present/ Patient status, and Future/Clinical decision support. Each workspace (rectangle icon) contains views (circle icons) that contain different configurations of data and functions.

When a workspace is selected, the correlating view icons are displayed.

- Use a swipe gesture or touch a workspace icon to go to a new workspace (swipe gesture: touch display and move finger tip left or right).
- When you navigate away from a workspace and then navigate back, the display will show the last view that was displayed from the workspace.
- If a view is not supported by the current patient type or software is not installed, it will not display.

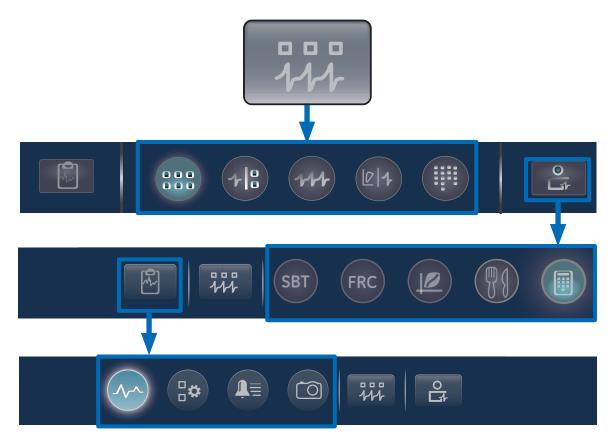


Figure 3.8 Navigation example; select a workspace (rectangle) to see correlating views (circle).

# **Present/Patient Status Workspace and Views**

The **Present/Patient Status** workspace shows the following views: Basic, Basic Waveform, Advanced Waveform, Splitscreen, and Charting. This workspace allows the user to choose the view in which they would like to see patient data displayed.

- Touch the icon to display the corresponding view.
- Use a swipe gesture to view and move to Past (Historical trends) and Future (Clinical decision support) workspaces.



# Present/Patient Status Workspace

# **Basic View**

Use the Basic view to see measured data in a large format that can be easily viewed from a distance.



**Note!** The patient status (airway pressure) bar is permanently displayed in the Basic View, as well as the Past (Historical trends) and Future (Clinical decision support) views. This allows the user to easily view patient airway pressure, tidal volume, and FiO<sub>2</sub>.



Figure 3.9 Basic View display screen



# **Basic Waveform View**

Use the Basic Waveform view to see patient waveforms and measured data.



**Note!** The airway pressure bar may be collapsed to expand the monitoring area when the Paw and Flow waveforms are displayed.



Figure 3.10 Basic Waveform View



# Advanced Waveform View

Use the Advanced Waveform view to see additional measured data associated with the patient waveforms.



**Note!** The airway pressure bar may be collapsed to expand the monitoring area when the Paw and Flow waveforms are displayed.



Figure 3.11 Advanced Waveform View



### **Splitscreen View**

Use the Splitscreen view to see spirometry, measured data, and waveforms. Select the upper right corner of the spirometry waveform to change settings.



**Charting View** 

**Note!** The airway pressure bar may be collapsed to expand the monitoring area when the Paw and Flow waveforms are displayed.



#### Figure 3.12 Splitscreen View

Use the Charting view to see a complete list of patient data. The airway pressure bar is permanently displayed to easily view patient airway and pressure settings, tidal volume and FiO<sub>2</sub>.

Men		Adult	<b>\</b>	No Alarms				Alarm Setu	P Auto PEEP	Vital P 0.1 Compaci	Manual ty Breath
Spiro	metry	Mech	/Spont	Timing	Pulmonary	Per W	/eight	Gases	Metabolics	Pav	N
Ppeak		MVexp mech	MVexp spont	I:E	c	MVexp/kg	MVexp spont/kg	FIO2		cmH	
22		9.9	0.00	1:2	21	0.019	0.000	65		60	
cmH2O											
Pmean											
8	4	450		0.9		0.9					
cmH2O										40	
PEEPe											
7		22	0	1:8							
cmH2O									ml/min/m2		Ppeak
MVinsp									VCO2/m2	20	
2.2	2.1			22		0.19	112				
l/min	l/min			/min							PEEP
VTinsp	VTexp			Cucle Time						0	
450	96			2.7							
ml	ml			5						VTexp	FiO2
										450	65
					StaticPEEPI					ml	%
					cmH2O						
Tube com	pensation	on								:>-	
			~		) (1 :) (		214) (#1	) 읍			
										15:5	3
Cui	rrent Mode	_	02	Pinsp	Rate	Tins		PEEP	Pmax	STANDBY	
A	C PC		5	15	22	0.9		7	55	Ŀ	<del>Ц</del>

Figure 3.13 Charting View

# Past/Historical Trends Workspace and Views

The Past/Historical trends workspace shows information for the following views: *Graphical trends, Numerical trends, Trends log*, and *Snapshot trends.* 

- Touch the icon to display the corresponding view.
- Use a swipe gesture to view and move to Present/Patient status or Future/Clinical Decision Support workspaces.



### Past/Historical Trends Workspace



### **Graphical Trends View**

Use the Graphical trends view to review historical waveforms and patient trends.



Figure 3.14 Graphical Trends View



# Numerical Trends View

Use the Numerical trends view to review patient ventilation modes and settings, measured data, and alarm settings.

Paw cmH20
60
Pmax
40
40
Ppeak
20
PEEP
o
VTexp FiO2
450 65
ml %
÷-
15:54
Pmax STANDBY
55 SIANDBY

Figure 3.15 Numerical Trends View



## Trends Log View

Use the Trends Log to review patient alarms and settings, and events that have occurred during ventilation.



Figure 3.16 Trends Log View

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# **Snapshot Trends View**

Use Snapshot trends to view saved patient data.



Figure 3.17 Snapshot Trends View

# Future/Clinical Decision Support Workspace and Views

The Future/Clinical Decision Support workspace shows the following views (if software is installed): SBT, FRC, Spirometry, Metabolics, and Calculations.

• Touch the view icon to display the corresponding view.

• Use a swipe gesture to move to Present/Patient Status or Past/HistoricalTrends workspaces and associated views.



### **Future/Clinical Decision Support**

### **SBT View**

Use the SBT view to evaluate spontaneous breathing trial data.



Figure 3.18 SBT View



SBT

# **FRC View**

Use the FRC view to evaluate and review patient respiratory data. The FRC view includes three tabs: Evaluate, FRC INview (FRC procedure), and PEEP INview (PEEP INview procedure).

### **Evaluate Tab**

Use the Evaluate tab to review respiratory data, including waveforms and measured data to determine if the patient is in steady state for optimal FRC results.



Figure 3.19 FRC Evaluate Tab



### **FRC INview Tab**

Use the FRC INview tab to perform an FRC INview procedure to measure the patient's FRC.

Menu	Adult ဂို ဂို	No Alarms			Alarm Setup	Ô2	Insp Hold Exp Hold	Manual Breath
Evalu	ate	FRC I	Nview	PE	EP INview		Pav cmH2	
FRC O2 60 % Interval Single	FRC - Bree 2000 ml 0 0 0 FRC ml PEEPe+i CmH20	30-Jan 133:16 1438 4+1	30 - Jan 13:16		Bree	eths 20	60 40 20	Pmox Ppeak PEEP
	Cstat ml/cmH20	46					vTexp 450 ml	FiO2 50 %
Assist control	off	VT VI	SBT FRC		PEEP	Pmax	:>- 16:05	;
Current Mode	50 %	475 ∞⊓	12 /min	1:2	Off	50 mH20		Å
		Figur	e 3.20 FRG	C INview 1	Tab			

### **PEEP INview Tab**

Use the PEEP INview tab to perform a PEEP INview procedure to determine the PEEP that optimizes the patient's FRC.



Figure 3.21 FRC PEEP INview Tab



### **Spirometry View**

Use the Spirometry view to evaluate and review graphs and data from spirometry and spirodynamic measurements. The Spirometry view includes the Spirometry tab and SpiroDynamics tab.



Figure 3.22 Spirometry Tab



Figure 3.23 SpiroDynamics Tab

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### **Metabolics View**

Use the Metabolics view to evaluate and review Metabolics measurements.



Figure 3.24 Metabolics View



#### **Calculations View**

Use the Calculations view to calculate and review data based on the ventilator, measured data, and laboratory blood gas analysis data.



Figure 3.25 Calculations View

# 4 Operation



# **Operation Objectives**

#### After completing this section, the participant will be able to:

- Turn the power to the ventilator on and off
- Prepare the system for a New Patient
- Utilize the system with Previous Patient data
- Utilize the system with Current Patient data
- Use the Circuit Setup menu
- Perform a System Check
- Set the Ventilator Data Source
- Access the System Menu
- Set a Ventilation and Backup Mode
- Set limit indicators
- Start patient ventilation
- Pause ventilation
- Utilize Park Circuit

# Power

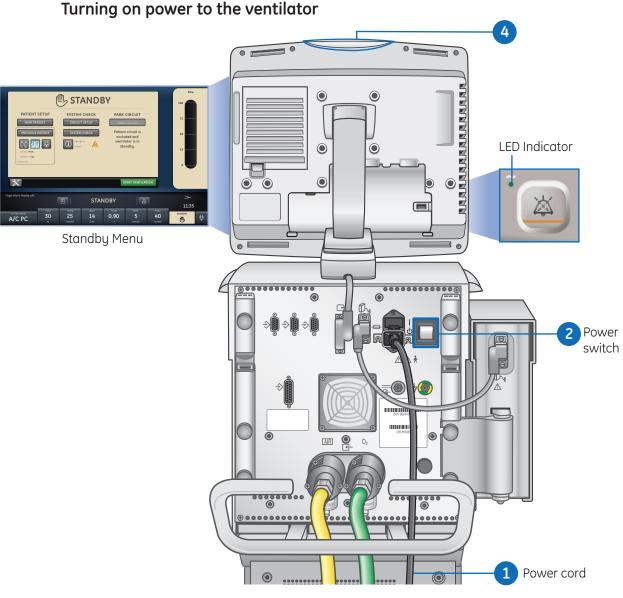


Figure 4.1 Power Switch Location

- 1. Plug the power cord into an electrical outlet.
  - The LED indicator illuminates (green) to indicate the main power is connected.
- 2. Press the power switch on the back of the ventilator to the **On** position.
  - The start-up screen appears while the system runs a series of automated self tests.
  - When the self tests pass, the system goes into Standby and the display shows the Standby menu.
- **3.** Listen for two distinctly different audio tones to sound to make sure the primary speaker and backup buzzer are working properly.
- **4.** Watch and verify the alarm light on the top of the display unit cycles through the following colors: blue, red, and yellow.



**Note!** If both the primary and backup audio tones do not sound or the alarm lights do not function correctly when the ventilator is powered on, take the ventilator out of service. Contact an authorized service representative to repair the system.

# Turning off power to the ventilator

The ventilator may only be turned off when in Standby, Configuration (Super User), or Service. If the ventilator is turned off during ventilation, an alarm sounds and ventilation and monitoring continue.



This ensures the ventilator cannot be accidentally shut off during ventilation.

Figure 4.2 Standby Quick Key

- 1. Disconnect the patient from the breathing circuit.
- Select Standby. Select Pause Ventilation to go to Standby. No ventilation will be delivered. Select Cancel to continue ventilation if a warning message is displayed.
- 3. Select *Pause Ventilation*. Monitoring and ventilation will stop.
- 4. Press the power switch on the back of the ventilator to the Off position.



**Note!** A Super User is anyone who has been given the configuration password and has the ability to set facility configuration defaults and system setting defaults.

# Patient Setup

# **New Patient**

After powering on the ventilator, the Standby menu displays. To prepare the ventilator for a New Patient, perform the following steps:



Figure 4.3 New Patient Menu

- 1. Select NEW PATIENT.
- 2. Select Adult, Pediatric, or Neonatal patient type.
- 3. Select Patient ID (identification).
  - Enter up to 10 characters and then select Confirm. (Only English alpha-numeric characters may be entered).



**Note!** To protect patient privacy, do not use the patient's name when entering the patient ID. Consider the facility's privacy policies when entering the patient ID.

- 4. Select Gender (male or female).
- 5. Select Height.
- 6. Select Weight.
  - The ventilator calculates and displays the patient weight in kilograms, the BSA (Body Surface Area), IBW (Ideal Body Weight), and a suggested VT (Tidal Volume).
  - IBW is available for adult patients only.
- **7.** Select (*Endotrach, Trach*, or ---). When --- is selected, the ventilator will not compensate for tube resistance.
- 8. Select Tube Diameter.
- 9. Verify and confirm settings.

### **Current Patient**

Use the *Current Patient* menu to update settings or change patient type from Pediatric to Adult or Adult to Pediatric. If Neonatal is installed, patient types may be changed from Neonatal to Pediatric or Pediatric to Neonatal.

- 1. Select Standby.
- 2. Select Current Patient. The Current Patient menu shows.
- 3. Select the desired patient type and adjust settings.

## **Previous Patient**

The *Previous Patient* button shows upon power up of the ventilator (instead of the Current Patient button) when previous patient data exists. Previous Patient allows the clinician to use the patient settings and alarm limits that were previously used and view trends and historical data. For example, if a patient is extubated, but fails to progress and needs to be reintubated, the clinician may use the previous patient settings.

From the Standby menu, select **PREVIOUS PATIENT.** 



**Note!** Previous Patient data is only saved when a normal shutdown sequence is performed. Abrupt or unexpected power loss will prevent this data from being saved.



Figure 4.4 Previous Patient Button

# System Check

# System Check Overview



Figure 4.5 System Check



**Note!** To help ensure the proper function of the system, it is highly recommended to complete the System Check between patients. Failure to complete a System Check may result in inaccurate delivery and monitoring. This may result in risk to the patient.

The ventilator should be fully cleaned and prepared for a patient before performing the System Check.

When started, the System Check runs automatically. Selecting the information icon will show the active progress in the System Check Details menu. The steps will show a green check mark (pass) or a red X (fail). When each check is completed, the next check begins.



**Note!** If a System Check is not completed for the current patient, the system uses the compliance and resistance data from the last completed system check for the set patient type for all internal compensations. If the current breathing circuit differs significantly from the previous circuit, differences in ventilation parameters due to changes in the compensation process are possible.

## **Circuit Setup**

Use the *Circuit Setup* menu to select settings that must be compensated for in patient circuit measurements. The HME and Humidifier (must include a heated expiratory limb) settings are selected in the Circuit Setup. For adult and pediatric patient types the default selection is HME. For the neonatal patient type, the Circuit Setup menu is not available and the Humidifier selection will always be used.



**Note!** Complete the System Check with the breathing circuit and accessories that will be used during ventilation. Changing the Circuit Setup will invalidate the current System Check results. Changing the patient circuit after completion of System Check will affect volume delivery and exhaled volume measurements. If any change is made to Circuit Setup or the patient circuit, repeat the System Check.

Circuit Setup should be checked when setting up a New Patient or a change has been made to the patient's circuit setup.

A yellow warning icon will replace the previous System Check status icon (pass or fail) when a change has been made in the Circuit Setup menu. The yellow warning icon indicates that a System Check should be performed.



Figure 4.6 Circuit Setup Button

- 1. Select *Circuit Setup*. The Circuit Setup menu displays.
- 2. Select the check box for the *HME* or *Humidifier*. Settings are confirmed when the setting is changed.
- 3. Select X to close the menu.

# Running a System Check



**Note!** The patient must not be connected to the ventilator while completing the System Check.

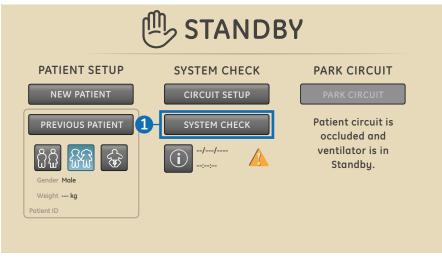


Figure 4.7 SYSTEM CHECK Button

- 1. From *Standby*, select *SYSTEM CHECK*. The Run System Check menu shows.
- 2. Attach the breathing circuit and all accessories that will be used to ventilate the patient.

Complete the System Check using the appropriate flow sensor per patient type. For example, use the neonatal flow sensor when completing a System Check for a neonatal patient.

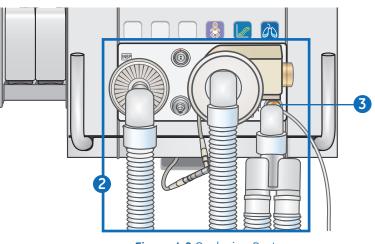


Figure 4.8 Occlusion Port

**3.** Occlude the patient wye using the occlusion port.



**Note!** When performing the Resistance Check, the wye-piece and all breathing accessories such as: D-lite (+)/Pedi-lite(+) sensor and HME should remain on the occlusion port.



Figure 4.9 System Check Details

- 4. Select Start. The System Check starts and shows the results of each check.
- **5.** Select the *information* icon to see the *System Check Details* menu. The System Check starts and shows the results of each check. Follow all on-screen instructions.
- **6.** As the System Check runs, the results of each check are displayed as a green check mark (pass) or red X (fail). If a check fails, a Help icon displays next to the failed check (red X
- 7. Select the *Help* icon to view possible causes and help for troubleshooting a failure.
- 8. When the System Check is complete, the *Final Result* line will display the patient type icon, a green check mark (pass) or red X (fail), and the date and time of the System Check.

# **Patient Ventilation**

# Setting the Ventilator Data Source

The data source is used to obtain patient monitoring parameters from either the ventilator or the airway module. See **Patient monitoring** for detailed information in the user's reference manual. See **Setting the ventilator data source** in the Neonatal Operation section of the user's reference manual

- 1. Select *Menu > System*. The System menu shows.
- 2. Select Data Source.
- 3. Select Ventilator or Airway Module to confirm settings.

If Ventilator is selected as the data source the Ventilator Data icon displays in the lower right corner of the display; the internal sensors of the ventilator will be the source for monitored data.

If Airway Module is selected as the data source and an airway module is installed and warmed up, the Airway Module (Patient) data icon displays in the lower right corner of the display. The airway module will be the first source for monitored data. If data is not available through the airway module, monitored data will come from the internal ventilator sensors.





#### Figure 4.10 Ventilator Data Icon

Figure 4.11 Airway Module Patient Data Icon



**Note!** When Airway Module is selected as the data source, the data source icon will not be updated until the module is able to provide data. This may take 2 to 5 minutes when a module is first installed into the module bay. Only data available from the installed airway module will be displayed on the ventilator, all other data will be from the ventilator. For example, if a module capable of measuring  $CO_2$  and  $O_2$  only is installed,  $CO_2$  and  $O_2$  data displayed will be from the module, all other data will be from the ventilator.

### System Menu

	Menu	Adult	No Alarms			*	δ <sub>α</sub>	Insp Hold Exp Hold	Manual Breath
1	System			Sys	tem				
2-	Procedures	–Data Source	Venti Module Tu		ovx M	1odule Version	4.5	Paw cmH2O	
3-	Lung Mechanics Nebulizer	- Calibrations	Airway			17:12:56	4.5	60 ——	
	Suction		Paux Purge Flo					40	Pmax Ppeak
	Minute Volu		Purge Flo	~				20	
4	5.9	—Display Brigh	itness	4				0	PEEP
6-		CARESCAPE F Software Vers		Air	Pressure: Pressure:	386 kpc 607 kpc		-5 VTexp 423 ml	Fi02 <b>40</b> %
		Running Hou Alititude:	rs: 10039 300	Bat m	tery Status:	Full charge			
	Leak compensation on	FiO2		Rate	I:E	PEEP	×	:>- 12:0	
	Current Mode	40 %	425 m	Rate <b>14</b> /min	1:2	реер 5 стн20	Ртах <b>35</b> стн20	Standby	Ψ

Figure 4.12 System Menu

The System menu contains settings for data source selection, calibration options, display brightness, and system information.

- Select *Menu > System*. The Airway Module type and software version number are shown under data source.
- 2. Select Data Source (Ventilator or Airway Module).
  - For Neonatal; select Ventilator or NFS
- 3. Select Calibrations (Airway Module, Paux Zero, or Purge Flow).
  - Select *Airway Module* to calibrate the airway module.
  - Select *Paux Zero*. A green check mark indicates Paux Zeroing calibration was successful.
  - Select **Purge Flow**. The Purge Flow check box may be checked or unchecked when performing a Paux Zero. Continuous purge flow will come from the Paux outlet when the Purge Flow check box is selected. A white check mark indicates Purge Flow is active.
- 4. Select *Display Brightness* to adjust the brightness level of the user interface.
  - Select brightness level of 1 (low) to 5 (high).
- 5. View system information: software version, service packet version, running hours, altitude, O<sub>2</sub> supply pressure, air supply pressure, and battery status.

# Setting a Ventilation and Backup Mode



Figure 4.13 Current Mode Button

Ventilation modes are selected through the *Current Mode* button. The selected ventilation mode shows with the corresponding mode settings.

Ventilation modes may be changed in *Standby* or during ventilation. Ventilation mode settings should be set prior to connecting a patient to the ventilator.

1. Select Current Mode.

Menu	Adult	No Alarms			Alarm Setup	Ô2	Insp Hold Exp Hold Breat	
Current Mode			Mode Se				Paw cmH20	
A/C VC A/C PC	Fi02 50	чт 475	Off	PS 5	Leak Comp			
A/C PRVC	% Breath Timi Rate	Tinsp	cmH20 Isnp Pause	cmH20	Trigger Comp Backup Mode		40 <b></b> Pma	
SIMV VC	12 /min Patient Syn Insp Trig	s	W % Bias Flow	PS Rise Time	A/C		20 Ppec	
CPAP/PS	2.0 ↓/mir	25	3.0 I/min	50 ms			0 PEEF	
срт 	Plimi 100 cmH2	50					VTexp Fi02 450 50 ml %	
Backup Settings							:>- 11:07	
		Cancel	Confirm				STANDBY	

Figure 4.14 Mode Settings Menu

- 2. Select the desired ventilation mode. The title of the vent mode shows in the *Mode Settings* menu along with the parameters for that mode.
- **3.** Depending upon the facility default setup for ventilation modes, the Mode Settings menu may contain two icons. The partial list icon represents the facility's set ventilation modes and the full list icon represents the full set of ventilation modes available. Set the desired settings for the ventilation mode and confirm.
- Select Leak Comp or Trigger comp if desired. Assist Control will also be available as a selection in the following ventilation modes: A/C VC, A/C PC, and A/C PRVC.
- **5.** Set the desired settings for the ventilation mode and confirm. When ventilator settings are confirmed, the Mode Settings menu closes and the selected ventilation mode shows in Current Mode.
- 6. To set a Backup Mode, select *Current Mode*.
- 7. Select *Backup Settings*. Set the desired settings for the backup mode and confirm.
- 8. Confirm all ventilation mode settings.

## Setting limit indicators

When adjusting ventilation mode settings, yellow and red visual indicators show when parameters are approaching their setting limits. Green visual indicators show the parameters are appropriate for the setting limits.

# Starting patient ventilation

Ventilation will not start until Start Ventilation is selected.



**Note!** Ensure that the ventilator battery is fully charged before starting patient ventilation.

NEW PATIENT     CIRCUIT SETUP     PARK CIRCUIT       PREVIOUS PATIENT     SYSTEM CHECK     Patient circuit is occluded and ventilator is in Standby.       Gender Male	PATIENT SETUP	SYSTEM CHECK	PARK CIRCUIT
Image: Standard Standa	NEW PATIENT	CIRCUIT SETUP	PARK CIRCUIT
응습을 없다.     ····································	PREVIOUS PATIENT	SYSTEM CHECK	
Gender Male		·····	ventilator is in
Weight kg	Gender Male		
	Weight kg		

Figure 4.15 Start Ventilation Button

- 1. From Standby, select START VENTILATION.
  - If the Start Ventilation button is green, a *System Check* has been completed for the current patient and when selected, will start ventilation.
  - If the Start Ventilation button is yellow, the *Complete System Check* warning alert will display the following:

Select *Continue* to bypass System Checkout and start ventilation. Select *Cancel* to remain in Standby.

2. After ventilation has started, connect the breathing circuit to the patient.



**Note!** It is recommended that System Check is completed prior to starting ventilation.

### **Pausing ventilation**



Note! The patient will not be ventilated when in Standby.

- 1. Disconnect the patient from the breathing circuit.
- 2. Select Standby.
- **3.** Select *Pause Ventilation* to go to Standby. No ventilation will be delivered. Select *Cancel* to continue ventilation if a warning message is displayed.
- 4. Select Pause Ventilation. Monitoring and ventilation will stop.

# **Park Circuit**

Park Circuit allows the patient circuit to be occluded without the ventilator alarming while in Standby. When the patient circuit is positioned on the occlusion port the display activates the **PARK CIRCUIT** selection.



**Note!** The patient will not be ventilated while the circuit is parked and in Standby.

- 1. Disconnect the patient from the breathing circuit.
- 2. Select Standby.
  - Select *Pause Ventilation* to go to Standby. No ventilation will be delivered. Select *Cancel* to continue ventilation if a warning message is displayed.
- 3. Select Pause Ventilation. Monitoring and ventilation will stop.
- 4. Occlude the patient circuit using the occlusion port.
- 5. Select PARK CIRCUIT. The display will show: Patient circuit is occluded and the ventilator is in Standby.



Figure 4.16 Park Circuit Activated

# 5 Alarms



# Alarms Objectives

After completing this section, the participant will be able to:

- Describe the components on the Alarm Bar
- Adjust an alarm limit with the Alarm Setup menu
- Utilize Auto Limits
- Describe the three alarm priorities
- Active Audio Pause
- Access the Alarm Setup menu via an active measured data alarm

# Alarms Overview

The alarm light can be seen from all sides of the ventilator, but messages can only be viewed from the front of the ventilator using the display.

During ventilation, there are two types of alarms that can occur, parameter and technical. Parameter alarms occur when the measured patient data is not in the range of the set limits. Technical alarms occur when an error condition is detected within the ventilator. A technical alarm may also occur when data cannot be interpreted or data is not available.

When an alarm occurs during ventilation, the ventilator emits an audible tone, flashes a light on the top of the display unit, and shows the alarm message on the screen.



Figure 5.1 Alarm Light and Alarm Bar

# Alarm Management

During ventilation, alarms are managed from the alarm bar, which gives a visual indication of the priority and type of alarm. Use the alarm bar to acknowledge alarms and access alarm settings. When a parameter alarm occurs, the measured data can be selected to quickly access the setting that is out of range.



**Note!** Do not set alarm limits to extreme values that can render the alarm system useless.

# Alarm Bar

The alarm bar gives a visual indication of parameter and technical alarms. The alarm bar includes audio pause, alarm status, and alarm setup.

- If there are no current active alarms or previous alarms requiring user acknowledgement, the alarm status shows No Alarms and the alarm bar is green. The alarm list is not available.
- If there are active alarms, the alarm status shows the alarm message for the most recent alarm with the highest priority. The alarm bar color shows the priority of the alarm. The alarm list contains a list of all active alarms, as well as previous alarms requiring user acknowledgement.
- If the alarm bar is grey, there are no active alarms but a previous alarm requires user acknowledgement.



Figure 5.2 Alarm Bar with No Active Alarms

- **1.** Audio pause
- 2. Alarm status
- 3. Alarm setup

Adjacent to Alarms is a number that shows how many alarms are in the list. Select the alarm status to show the list of alarm messages. The alarm messages are in the order of when the alarm occurred, with the most recent alarm shown at the top of the list. In addition, each alarm in the list has a timestamp to show when it occurred.

When the alarm list is expanded, select the question mark next to an alarm to show details about the alarm. The detailed information gives a description of the cause and what action is necessary to correct the alarm condition.

Alarm messages that are grey will show in the list after the condition is corrected and stay until they are viewed in the alarm list. When the list is closed, these messages are removed from the list and are available in the Trend log.



Figure 5.3 Alarm Bar with Active Alarms

- **1.** Audio pause timer
- 2. Active alarm count

# Alarm Setup

Alarm limits and other alarm settings can be adjusted in the Alarm Setup menu.

	EtCO2 lov	1		Alarm Setu	P		_
					Low	Current	High
1	Apnea Time	30	Ppeak	cmH20	10		40
			HVexp	I/min	2.8	5.8	7.5
			VTexp	ml	Off	323	400
			RR	/min	10	18	25
			EtCO2	%	1.0	3.2	4.5
2—	— Alarm Light Brightness	3	Cz02	%	Off	44	Off
		$\equiv$	HO2	%	19	45	56
3-	Alarm Volume	2	PEEPi	cmH20		•	Off
4-	High Alert Audio	20	Paux	cmH20		28	40
	Alarm Limits	<ul> <li>✓</li> </ul>	PEEPe	cmH20	Off	1	10
			Lock Limit	%		15	50
			Auto Llm	its			×

Figure 5.4 Alarm Setup Menu

- 1. Apnea Time: Set Apnea time up to 60 seconds.
- **2. Alarm Light Brightness:** Set the brightness level of the alarm light. The range is 1 (low) to 5 (high).
- 3. Alarm Volume: Set the volume of the alarm tone. The range is 1 (low) to 5 (high).
- 4. High Alert Audio: Set the delay time in which a high priority alarm must be resolved or acknowledged before the audio tone pitch and volume increase to the maximum level. The range is 0 to 30 seconds or Off. A general message shows when High Alert Audio is set to off.

Select either the low or high alarm limit, and then use the Trim Knob to adjust the setting.

Alarm setting changes that are not confirmed prior to the end of a timeout period are cancelled.



**Note!** Alarm limits for EtCO<sub>2</sub>, EtO<sub>2</sub>, and PEEPi are only available when an airway module with these measurement capabilities is installed. If the patient type is Neonatal, these alarm limits are not shown.

### Auto limits

Use the Auto Limits button to expand current alarm limits. This feature is only available while ventilating a patient, and may be useful when multiple alarms are occurring.

Select Auto Limits to change the alarm limits for the following measured data values.

- MVexp: Low and High
- VTexp: Low and High
- Rate: Low and High
- EtCO2: Low and High
- **PEEPe:** Low and High

The alarm setting change is dependent on the current measured data. An alarm limit set to Off will not change when Auto Limits is selected.

# **Alarm Priority**

Audible and visual indicators tell the priority of the alarm.

Priority	Color	Light	Tone
High	Red	Flashes red	Series of five tones twice
Medium	Yellow	Flashes yellow	Series of three tones
Low	Blue	Solid blue	Single tone

For medium and high priority alarms, the alarm tone is repeated until audio pause is selected or the alarm condition is resolved. When high priority alarms are not resolved within the set high alert audio time limit, the pitch and volume of the tone increases to the maximum audio level.

When more than one alarm occurs at the same time, the alarm bar, alarm light, and audible alarm tone indicates the highest priority alarm.

The color on the right side of the alarm light shows the priority of the alarm. The left side of the alarm light is blue when audio pause is active.

Some medium priority and high priority alarms are de-escalated and change to low priority alarm when audio pause is selected. Until the de-escalated alarm condition is resolved, the low priority alarm stays active.

### **Audio Pause**

Audio pause temporarily mutes the audible tone of an alarm for two minutes.

To pause audio, select the audio pause icon on the alarm bar or press the audio pause hard key on the front of the display. When audio pause is selected, a timer above audio pause in the alarm bar starts to count down from two minutes. If the alarm is still active or a new alarm occurs after the timer expires, the alarm tone becomes audible for the highest priority alarm.

Select audio pause while the timer is counting down to cancel audio pause; the alarm tone then becomes audible.

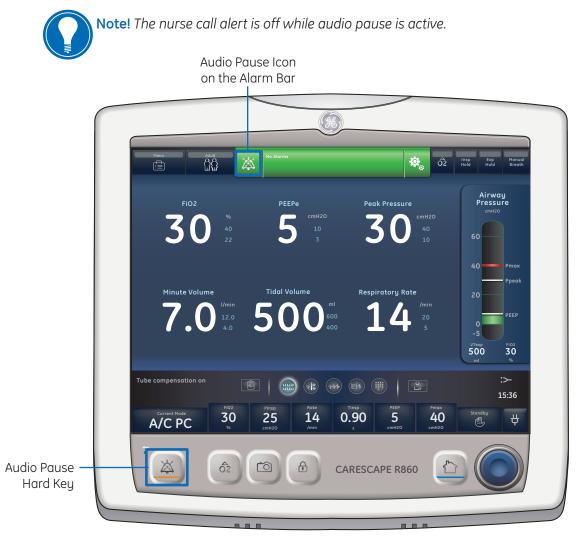


Figure 5.5 Audio Pause Locations

# Measured Data Alarms

When an alarm occurs for measured data, the number and alarm limits are shown with a border around them. The color of the border and the alarm limit (when in the Alarm Setup menu) shows the priority of the alarm. Select within the border of the active alarm to open the Alarm Setup menu. If necessary, use the Trim Knob to adjust the setting for the alarm limit.



Figure 5.6 Border of an Active Alarm

# 6 Ventilation Modes



# Ventilation Modes Objectives

After completing this section, the participant will be able to:

- Describe the difference between invasive and non-invasive ventilation
- Describe the difference between mechanical and spontaneous breaths
- Describe the following parameters: PEEP, Pressure Support, Flow and Pressure Triggering and Breath Timing Preferences
- Describe the purpose of the following ventilation mode features: Tube Compensation, Assist Control, Leak Compensation, Trigger Compensation, and Backup Mode
- Describe each of the following modes:
  - Assist control volume control
  - Assist control pressure control
  - Assist control pressure regulated volume control
  - Synchronized intermittent mandatory ventilation volume control
  - Synchronized intermittent mandatory ventilation pressure control
  - Synchronized intermittent mandatory ventilation pressure regulated volume control
  - Continuous positive airway pressure / pressure support
  - BiLevel airway pressure ventilation
  - BiLevel airway pressure ventilation volume guaranteed
  - Airway pressure release ventilation
  - Volume Support
  - Non-invasive ventilation
  - Spontaneous breathing trial

### Ventilation Mode Basics

### Invasive and non-invasive ventilation

The ventilator provides several standard modes for invasive ventilation and non-invasive modes (nCPAP for neonates).

- Invasive ventilation modes provide a range of patient support, from fully controlled mechanical breaths to pressure supported breaths for spontaneously breathing patients.
- Non-invasive modes are intended to be used for spontaneously breathing patients only.



**Note!** See ventilation mode descriptions for details about the settings and features each mode provides.

The primary difference between setting up a patient for invasive and non-invasive ventilation is the accessories used.

- Invasive ventilation is delivered through an artificial airway (e.g., endotracheal tube), which is inserted into the patient's trachea.
- Non-invasive ventilation is delivered using positive-pressure ventilation through an
  accessory such as a nasal mask or mouthpiece. These accessories are often attached
  to the patient's head to increase the quality of the airway seal to minimize airway
  leaks. Non-invasive ventilation masks should be non-vented and must not include an
  entrainment (inspiratory) valve. Patient circuits for use with non-invasive ventilation
  must be dual-limb with connections for both the inspiratory and expiratory ports of
  the ventilator.

### **Mechanical and Spontaneous Breaths**

The ventilator offers multiple ventilation modes, which support mechanical and spontaneous breaths. Mechanical breaths are controlled by the ventilator. The ventilator uses the selected mode settings to determine the characteristics of the breath such as timing, volume, and pressure. Depending on which mode is set, mechanical breaths are initiated by the ventilator or the patient.

- Ventilator-initiated: the ventilator uses the set respiratory rate to initiate a breath.
- Patient-initiated: the patient activates the set inspiratory trigger (flow or pressure) to initiate a breath.

Spontaneous breaths are initiated and controlled by the patient.



**Note!** In ventilation modes with a PS setting, spontaneous breaths are pressuresupported at the PS level.

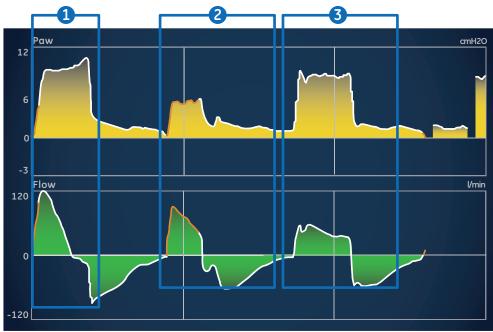
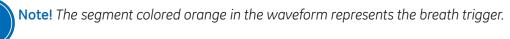


Figure 6.1 Breath Types

- 1. Patient-initiated, mechanical breath
- 2. Spontaneous pressure supported breath
- 3. Ventilator-initiated, mechanical breath



### **Ventilation Mode Settings**

Ventilation mode settings are separated into four categories:

- Main Parameters
- Breath Timing
- Patient Synchrony
- Safety

Each ventilation mode has a unique set of settings. See each ventilation mode description for a list of applicable settings. Quick Keys on the lower portion of the display provide access to ventilation mode settings that are likely to be adjusted frequently. The remaining settings can be adjusted in the Current Mode > Mode Settings menu.



**Note!** When changing ventilation modes, some settings may change if the two modes do not share the same limits or increments.

- When the setting is greater than the maximum value allowed inthe new mode, the maximum value is set.
- When the setting is less than the minimum value of the new numeric range, the minimum value is set.
- When the setting is between increments, the value is rounded to the increment above or below it.

### **Positive end Expiratory Pressure (PEEP)**

PEEP is the low pressure maintained in the patient's airway during the expiratory phase. PEEP prevents the patient's lungs from collapsing at the end of expiration. Maintaining a PEEP level improves the possibility of increasing oxygenation. PEEP (or the equivalent setting of Plow) is available in all ventilation modes.

### **Pressure Support**

Pressure support provides additional pressure during the inspiratory phase of spontaneous breaths in spontaneous breathing modes. The PS setting is available in the following ventilation modes:

- CPAP/PS
- SIMV VC
- SIMV PC
- SIMV PRVC
- BiLevel
- BiLevel VG
- NIV
- SBT

The maximum duration of the inspiratory phase for pressure supported breaths is Tsupp or 4 seconds for adults, 1.5 seconds for pediatrics, and 0.8 seconds for neonates. The inspiratory phase of pressure-supported breaths ends when one of the following occurs:

- Set Exp Trigger is detected.
- Set VT is delivered (VS mode only).
- Pressure exceeds PEEP + PS + 2.5 cmH2O.
- Set Tsupp is reached

### Flow and Pressure Triggering

The ventilator detects a patient's spontaneous breathing effort based on changes in flow or pressure.

- Flow trigger: A breath is delivered when the patient's inspiratory effort reaches the Insp Trigger setting.
- **Pressure trigger:** A breath is delivered when the patient's negative airway pressure (below PEEP) reaches the Insp Trigger setting.

To set a flow or pressure trigger, adjust the Insp Trigger setting.

- To set a flow trigger, select Current Mode, select the trigger setting, set a positive value using the Trim Knob and confirm.
- To set a pressure trigger, select Current Mode, select the trigger setting, set a negative value using the Trim Knob and confirm.

The ventilator synchronizes mechanical breaths with patient triggers when in the following modes:

- SIMV VC
- SIMV PC
- SIMV PRVC
- BiLevel
- BiLevel VG

And when assist control is active in the following modes:

- A/C VC
- A/C PC
- A/C PRVC

### **Breath Timing Preferences**

The parameters used to represent the timing of a delivered breath or inspiratory phase of a delivered breath may be selected by the facility.



**Note!** Timing and Flow default settings may be changed by a Super User. **Note!** Selecting a breath timing for the modes listed in the table will not affect other ventilation modes.

## Ventilation Mode Features

### **Tube Compensation**

When a patient is intubated, the endotracheal or tracheostomy tube creates resistance in the airway. Tube compensation provides additional pressure to compensate for the difference between the lung pressure and breathing circuit pressure during the inspiratory phase of pressure-controlled and pressure-supported breaths.

Tube compensation can be used to offset all or a percentage of the additional resistive pressure created by the endotracheal tube.



**Note!** To set Tube compensation, a Tube Type and Tube Diameter must be set in the New Patient or Current Patient menu.

WARNING! Tube compensation increases the pressure delivered to the patient. The pressure delivered with tube compensation is limited to Pmax - 5 cmH2O. Make sure that Pmax is set appropriately for the patient when using tube compensation.

To set Tube Compensation, select Current Mode > Mode Settings and select Tube Comp. A general message shows when tube compensation is on.



**Note!** The options for tube compensation are: Endotrach, Trach, or ---. When --- is selected, the ventilator will not compensate for tube resistance.

### **Assist Control**

Assist control allows the ventilator to synchronize mechanical breaths to the patient's spontaneous efforts and the patient to trigger additional mechanical breaths to the set respiratory rate in the following ventilation modes:

- A/C VC
- A/C PC
- A/C PRVC

When the patient initiates a breath with assist control enabled, the ventilator delivers a breath based on the mode settings. After a patient-initiated mechanical breath, the ventilator may delay the delivery of the next mechanical breath to prevent two mechanical breaths from being delivered consecutively (breath stacking). Under certain conditions, such as high spontaneous breathing rates or high leakage, the rate of mechanical breaths may not meet the set respiratory rate.



**Note!** Under certain conditions, such as high spontaneous breathing rates or high leakage, the rate of mechanical breaths may not meet the set respiratory rate.

A general message shows when assist control is off. When assist control is off, the patient is able to draw spontaneous breaths at the set PEEP level between mechanical breaths.

To set Assist Control, select *Current Mode > Mode Settings* and select *Assist Control* (On or Off).

### **Leak Compensation**

# **WARNING!** The exhaled volume of the patient can differ from the measured exhaled volume due to leaks.

To set Leak Compensation, select *Current Mode > Mode Settings* and select *Leak Comp*. A general message shows when leak compensation is on.

When the ventilator detects a leak in the breathing circuit, and leak compensation is active, the ventilator will respond in the following ways:

• Flow and volume waveforms and measured volume data are adjusted to account for leaks.

In the following volume-controlled modes, the ventilator adjusts the tidal volume delivered to compensate for leaks:

- A/C VC
- A/C PRVC
- SIMV VC
- SIMV PRVC
- BiLevel VG
- VS

The maximum tidal volume adjustment depends on the patient type:

- Adult: 25% of the set tidal volume
- Pediatric: 100% of the set tidal volume or 100 ml, whichever is less
- Neonatal: 100% of the set tidal volume

### **Trigger Compensation**

Leaks can cause the ventilator to initiate breaths automatically (autotriggering). Trigger compensation adjusts the flow trigger to compensate for leaks, reducing the need to manually adjust the Insp Trigger setting to prevent auto-triggering.

Trigger compensation is available in all ventilation modes. To set trigger compensation, select *Current Mode > Mode Settings*, and select *Trigger Comp*.

### **Backup Mode**

Backup mode is available if the ventilator detects insufficient ventilation in modes that allow spontaneous breaths. When enabled, the ventilator automatically enters the set Backup mode if either of the following occur:

- The Apnea alarm is activated.
- The patient's expired minute volume (MVexp) is below 50% of the set low MVexp alarm.

The set Backup mode is shown under the Backup mode check box in *Current Mode > Mode Settings*. To enable Backup mode, select the check box.

Backup settings are a subset of available settings in each ventilation mode. Adjust Backup settings in *Current Mode > Mode Settings > Backup Settings*.



**Note!** Settings that are not designated as Backup settings remain at the current value when the ventilator transitions to the set Backup mode.

**WARNING!** Ensure that all users at the facility have been trained and notified of the facility default Backup mode settings. Before deactivating backup ventilation for a specific mode, ensure that all users at the facility have been trained and notified of these settings.

Backup mode is available in the following ventilation modes:

- SIMV VC
   BiLevel VG
- SIMV PC CPAP/PS
- SIMV PRVC VS
- BiLevel APRV

The following ventilation modes may be set as the Backup mode:

- A/C VC SIMV PC
- A/C PC
   SIMV PRVC
- A/C PRVC BiLevel
- SIMV VC
   BiLevel VG

### Assist Control Volume Control (A/C VC)

During A/C VC mode, the ventilator delivers mechanical breaths of the set tidal volume (VT) at intervals based on the set respiratoryrate (Rate).



**Note!** The amount of pressure required to deliver the tidal volume depends on the patient's lung compliance and resistance.

**Note!** Actual ventilation settings may be different if breath timing settings (Timing and Flow) have been changed.

In A/C VC mode, assist control is available to synchronize mechanical breaths to the patient's spontaneous efforts and to allow triggering of additional mechanical breaths. With assist control disabled, the patient can initiate spontaneous breaths at the set PEEP level during the expiratory phase.



Note! To set Assist Control, select Current Mode > Mode Settings and select Assist Control.

During A/C VC mode, the ventilator calculates an inspiratory flow based on the set tidal volume, inspiratory time, and Tpause. Constant gas flow to the patient is maintained during the inspiratory phase while the airway pressure is below the pressure limit (Plimit) setting. If the Plimit setting is reached, the gas flow is reduced to maintain the Plimit level for the remainder of the inspiratory period. The ventilator monitors delivered tidal volume and adjusts the delivered inspiratory flow as needed to maintain the set tidal volume for subsequent breaths.

Note! Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

Category	Settings	1.	Airway pressure
Main Parameters	FiO2	2.	Inspiratory time (
	VT	3.	Inspiratory pause
	PEEP	4.	Expiratory time (1
	Flow	5.	PEEP
Breath Timing	Rate	6.	Flow waveform
	I:E, Tinsp, or Tpause	7.	Tidal volume (VT)
	Insp Pause		
Patient Synchrony	Insp Trigger		
	Bias Flow		
Safety	Plimit		
	Pmax		
anssaud	3 Texp 3 4		5 PEEP
			Tir

### The following settings are available in A/C VC mode:

- (Paw) waveform
- (Tinsp)
- e (Tpause)
- (Texp)
- -)



# Assist control pressure control (A/C PC)

During A/C PC mode, the ventilator delivers mechanical breaths at the set inspiratory pressure level (Pinsp) for a set inspiratory time (Tinsp) at intervals based on the set respiratory rate (Rate).



**Note!** The tidal volume delivered depends on the compliance of the patient's lungs.

In A/C PC mode, assist control is available to synchronize mechanical breaths to the patient's spontaneous efforts and to allow triggering of additional mechanical breaths. With assist control disabled, the patient can initiate spontaneous breaths at the set PEEP level during the expiratory phase.



**Note!** To set Assist Control, select **Current Mode > Mode Settings** and select **Assist Control.** 

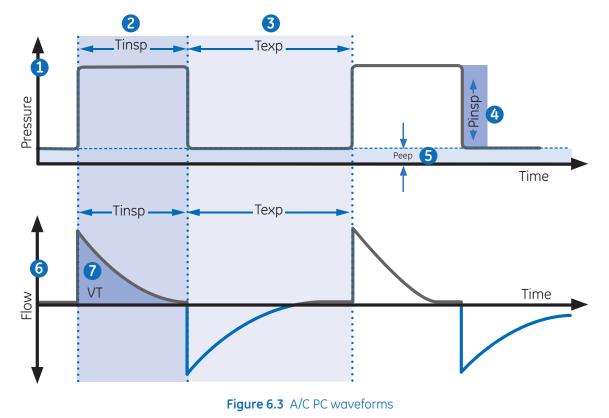
During A/C PC, the gas flow to the patient decreases after the pressure level reaches the pressure setting (Pinsp). A high initial flow pressurizes the circuit to the set inspiratory pressure (Pinsp). The flow then decreases to maintain the set pressure for the remaining inspiratory time.



**Note!** Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

Category	Settings
Main Parameters	FiO2
	PInsp
	PEEP
Breath Timing	Rate
	I:E or Tinsp
Patient Synchrony	Insp Trigger
	Bias Flow
	Rise Time
Safety	Pmax

### The following settings are available in A/C PC mode:



- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- **3.** Expiratory time (Texp)
- 4. Inspiratory pressure (Pinsp)
- 5. PEEP
- 6. Flow waveform
- 7. Tidal Volume (VT)

# Assist Control Pressure Regulated Volume Control (A/C PRVC)

During A/C PRVC mode, the ventilator delivers mechanical breaths of the set tidal volume (VT) at intervals based on the set respiratory rate (Rate). For each breath, the ventilator adjusts the inspiratory pressure to use the lowest pressure required to deliver the tidal volume.



**Note!** Actual ventilation settings may be different if breath timing settings (Timing and Flow) have been changed.

To determine the patient's lung compliance, the ventilator delivers volume-controlled ventilation for 10 seconds or two breath periods, whichever is longer when the mode is initiated. Based on the patient's lung compliance, the inspiratory pressure is established and used for the subsequent breaths.

The ventilator uses the following pressure range when adjusting inspiratory pressure:

- Low limit: PEEP + Pmin
- High limit: Pmax 5 cmH<sub>2</sub>O

The difference in inspiratory pressure between breaths does not exceed  $\pm$  3 cmH<sub>2</sub>O.



**Note!** If a high airway pressure alarm is active for the current breath, the next breath's pressure target is 0.5 cmH2O lower.

In A/C PRVC mode, assist control is available to synchronize mechanical breaths to the patients spontaneous efforts and to allow triggering of additional mechanical breaths. With assist control disabled, the patient could draw spontaneous breaths at the set PEEP level during the expiratory phase.

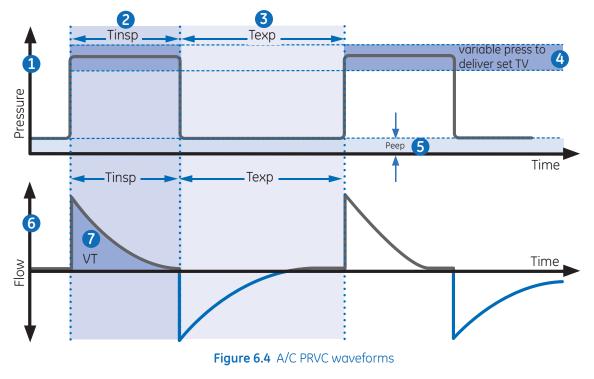


**Note!** To set Assist Control, select **Current Mode > Mode Settings** and select **Assist Control.** 

Note! Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

The following settings are available in A/C PRVC mode:

Category	Settings
Main Parameters	FiO2
	VT
	PEEP
Breath Timing	Rate
	I:E, Tinsp, or Tpause
Patient Synchrony	Insp Trigger
	Bias Flow
	Rise Time
Safety	Pmax
	Pmin



- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- **3.** Expiratory time (Texp)
- 4. Variable pressure to deliver set TV
- 5. PEEP
- 6. Flow waveform
- 7. Tidal volume (VT)

# Synchronized Intermittent Mandatory Ventilation Volume Control (SIMV VC)

During SIMV VC mode, the ventilator delivers synchronized volumecontrolled breaths at the set respiratory rate (Rate). All other spontaneous efforts are delivered as pressure-supported breaths.



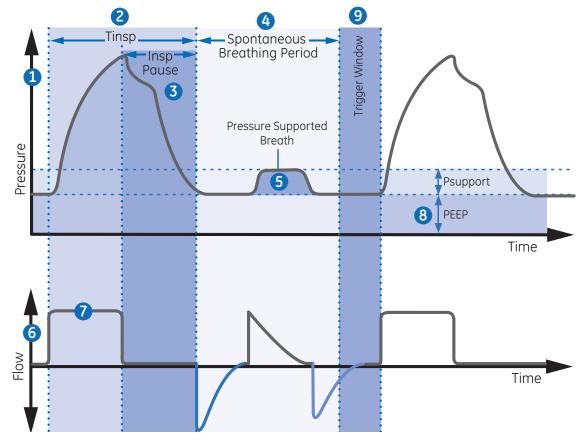
**Note!** Actual ventilation settings may be different if breath timing settings (Timing and Flow) have been changed.

**Note!** Backup ventilation is available in SIMV VC mode. Set a Backup Mode in **Current Mode > Mode Settings.** 

**Note!** Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

#### The following settings are available in SIMV VC mode:

Category	Settings
Main Parameters	FiO2
	Flow
	VT
	PEEP
	PS
Breath Timing	Rate
	Tinsp or Tpause
	Insp Pause
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
Safety	Plimit
	Pmax





- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- 3. Inspiratory pause (Insp Pause)
- 4. Spontaneous breathing period
- 5. Pressure-supported breath
- 6. Flow waveform
- 7. Tidal volume (VT)
- 8. PEEP
- 9. Trigger window

# Synchronized Intermittent Mandatory Ventilation Pressure Control (SIMV PC)

During SIMV PC mode, the ventilator delivers synchronized pressure-controlled breaths, the number of which is determined by the set respiratory rate (Rate). All other spontaneous efforts are delivered as pressure-supported breaths.

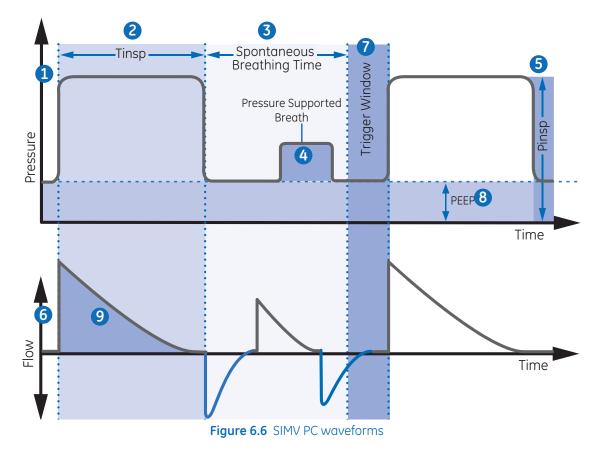


**Note!** Backup ventilation is available in SIMV PC mode. Set a Backup Mode on the **Current Mode > Mode Settings** menu.

**Note!** Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

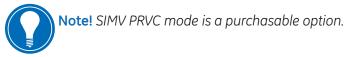
The following settings are available in SIMV PC mode:

Category	Settings
Main Parameters	FiO2
	Pinsp
	PEEP
	PS
Breath Timing	Rate
	Tinsp
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
Safety	Pmax



- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- 3. Spontaneous breathing time
- 4. Pressure-supported breath
- 5. Inspiratory pressure (Pinsp)
- 6. Flow waveform
- 7. Trigger window
- 8. PEEP
- 9. Tidal Volume (VT)

# Synchronized Intermittent Mandatory Ventilation Pressure Regulated Volume Control (SIMV PRVC)



During SIMV PRVC mode, the ventilator delivers synchronized pressure regulated volume controlled breaths at the set respiratory rate (Rate). For each mechanical breath, the ventilator adjusts the inspiratory pressure to use the lowest pressure required to deliver the tidal volume. All other spontaneous efforts are delivered as pressure-supported breaths.

To determine the patient's lung compliance, the ventilator delivers volume controlled ventilation for 10 seconds or two inspiratory periods, whichever is longer when the mode is initiated. Based on the patient's lung compliance, the inspiratory pressure is established and used for subsequent breaths.

The ventilator uses the following pressure range when adjusting inspiratory pressure:

- Low limit: PEEP + Pmin
- High limit: Pmax 5 cmH<sub>2</sub>O

The difference in inspiratory pressure between breaths does not exceed  $\pm 3$  cmH<sub>2</sub>O.



**Note!** If a high airway pressure alarm is active for the current breath, the next breath's pressure target is 0.5 cmH<sub>2</sub>O lower.

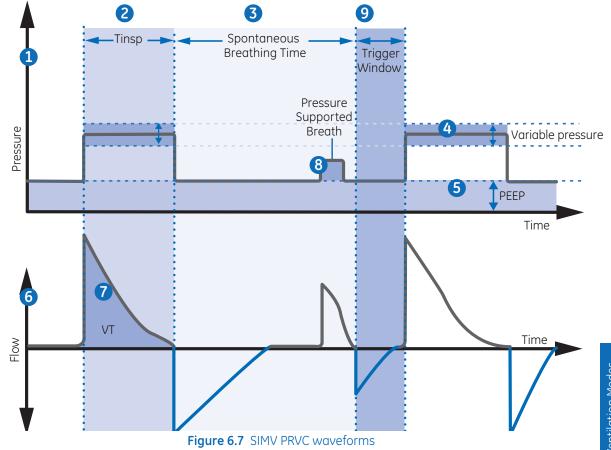
**Note!** Backup ventilation is available in SIMV PRVC mode. To set a Backup Mode, select **Current Mode > Mode Settings** and select **Backup Mode**.

**Note!** Tube Comp, Leak Comp, and Trigger Comp modes may be set if desired.

### The following settings are available in SIMV PRVC mode:

Category	Settings
Main Parameters	FiO2
	PEEP
	PS
	VT
Breath Timing	Rate
	Tinsp
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
	Rise Time
Safety	Pmax
	Pmin

- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- 3. Spontaneous breathing time
- 4. Variable pressure
- 5. PEEP
- 6. Flow waveform
- 7. Tidal volume (VT)
- 8. Pressure supported breath
- 9. Trigger window



### Continuous Positive Airway Pressure/Pressure Support (CPAP/PS)

CPAP/PS mode is intended to be used on spontaneously breathing patients. During CPAP/PS mode, the ventilator maintains a PEEP level and provides pressure support (PS). The patient initiates spontaneous breaths and determines respiratory rate, timing, and tidal volume.

When the Minimum Rate is set during CPAP/PS, the ventilator will deliver a pressure controlled mechanical breath if the patient's spontaneous respiratory rate is less than the Minimum Rate. The mechanical breath will be delivered at the Backup Pinsp pressure setting for the time duration of the Backup Tinsp setting.

To deliver mechanical breaths during CPAP/PS mode, a Super User can enable the following settings.

- Minimum Rate
- Backup Pinsp
- Backup Tinsp

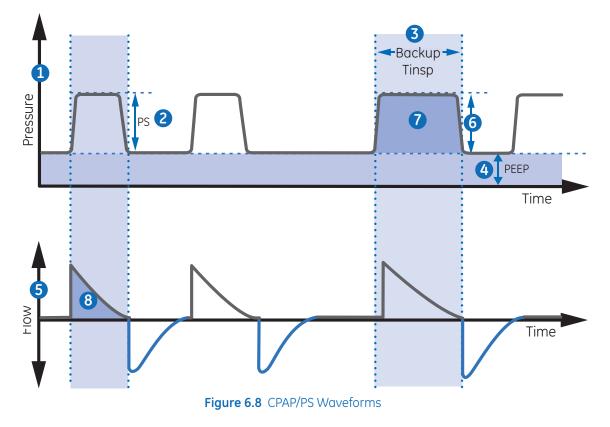


**Note!** Backup ventilation is also available in CPAP/PS mode. To set a Backup Mode, select Current Mode > Mode Settings and select Backup Mode.

Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

#### The following settings are available in CPAP/PS mode:

Category	Settings
Main Parameters	FiO2
	PEEP
	PS
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
Safety	Pmax
	Minimum Rate
	Backup Tinsp
	Backup Pinsp



- 1. Airway pressure (Paw) waveform
- 2. Pressure support (PS)
- 3. Inspiratory time (Backup Tinsp)
- 4. PEEP
- 5. Flow waveform
- 6. Backup Pinsp
- 7. Minimum rate backup breath
- 8. Tidal Volume (TV)

# BiLevel Airway Pressure Ventilation (BiLevel)

Note!BiLevel mode is a purchasable option.

During BiLevel mode, the ventilator alternates between the set PEEP level and the set inspiratory pressure level (Pinsp) based on the set Rate and Tinsp. The patient can breathe spontaneously at either level. If the patient initiates a breath at the PEEP level, a pressure supported breath at the set PS setting is delivered.

If the patient initiates a spontaneous breath during the high pressure period (Tinsp), the level of inspiratory pressure provided depends on the PS and Pinsp settings.

- If PS is greater than Pinsp, the ventilator provides the additional pressure to support the breath.
- If Pinsp is greater than PS, the ventilator provides no additional pressure support.

If the patient initiates a spontaneous breath near the end of Thigh, the ventilator continues to deliver at Pinsp or PS, whichever is greater, until it detects the Exp Trigger or the maximum inspiratory duration for a pressure-supported breath. The ventilator will then transition to the PEEP level.



**Note!** Backup ventilation is available in BiLevel mode. To set a Backup Mode, select **Current Mode > Mode Settings** and select **Backup Mode**.

Category	Settings
Main Parameters	FiO2
	Pinsp
	PEEP
	PS
Breath Timing	Rate
	Tinsp
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
Safety	Pmax

### The following settings are available in BiLevel mode:

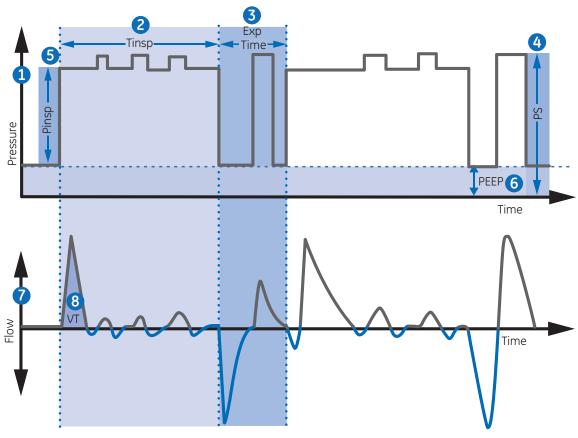


Figure 6.9 BiLevel Waveforms

- **1.** Airway pressure (Paw) waveform
- 2. Tinsp
- 3. Exp time
- 4. Pressure Support (PS)
- 5. Pinsp
- 6. PEEP
- 7. Flow waveform
- 8. Tidal Volume (VT)

# BiLevel Airway Pressure Ventilation Volume Guaranteed (BiLevel VG)

**Note!** BiLevel VG mode is a purchasable option.

During BiLevel VG mode, if the patient initiates a breath at the PEEP level, a pressuresupported breath at the PS setting is delivered. The ventilator alternates between a set PEEP and the minimum pressure to deliver the set tidal volume (VT) based on the set Rate and Tinsp.

To determine the patient's lung compliance, the ventilator delivers volume-controlled ventilation for 10 seconds or two inspiratory periods, whichever is longer when the mode is initiated. Based on the patient's lung compliance, the inspiratory pressure is established and used for subsequent breaths.

The ventilator uses the following pressure range when adjusting inspiratory pressure:

- Low limit: PEEP + Pmin
- High limit: Pmax 5 cmH<sub>2</sub>O

The difference in inspiratory pressure between breaths does not exceed  $\pm 3$  cmH<sub>2</sub>O.

If the patient initiates a breath at the PEEP level, a pressure supported breath at the set PS setting is delivered.



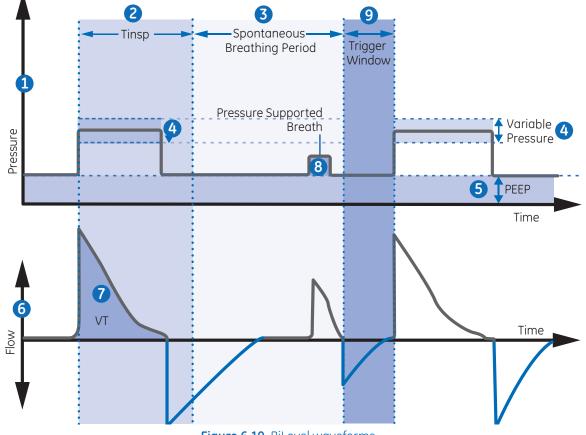
**Note!** If a high airway pressure alarm is active for the current breath, the next breath's pressure target is  $0.5 \text{ cmH}_2O$  lower.

**Note!** Backup ventilation is available in BiLevel VG mode. To set a Backup Mode, select **Current Mode > Mode Settings** and select **Backup Mode**.

**Note!** Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

### The following settings are available in BiLevel VG mode:

Category	Settings
Main Parameters	FiO2
	VT
	PEEP
	PS
Breath Timing	Rate
	Tinsp
Patient Synchrony	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
	Rise Time
Safety	Pmax
	Pmin



- Figure 6.10 BiLevel waveforms
- 1. Airway pressure (Paw) waveform
- 2. Inspiratory time (Tinsp)
- 3. Spontaneous breathing period
- **4.** Variable Pressure
- 5. PEEP
- 6. Flow waveform
- 7. Tidal volume (VT)
- 8. Pressure-supported breath
- 9. Trigger window

# Airway Pressure Release Ventilation (APRV)

**Note!** APRV mode is a purchasable option.

APRV mode is intended to be used on spontaneously breathing patients. During APRV mode,the ventilator alternates between a set high (Phigh) and low (Plow) pressure level. The ventilator will deliver the set (Phigh) pressure for the set (Thigh) duration of time. The ventilator will deliver the set (Plow) pressure for the set (Tlow) duration of time. The patient can initiate spontaneous breaths at either level.

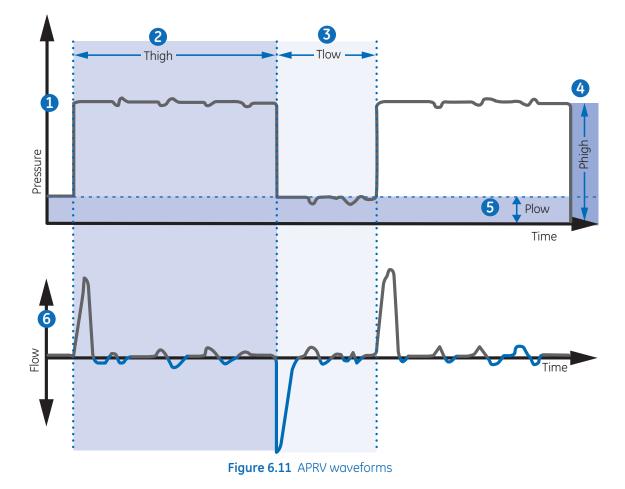


**Note!** Backup ventilation is available in APRV mode. To set Backup Mode, select **Current Mode > Mode Settings** and select **Backup Mode**.

**Note!** Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

Category	Settings
Main Parameters	FiO2
	Phigh
	Plow
Breath Timing	Thigh
	Tlow
Patient Synchrony	Insp Trigger
	Bias Flow
	Rise Time
Safety	Pmax

The following settings are available in APRV mode:



- 1. Airway pressure (Paw) waveform
- 2. Thigh
- 3. Tlow
- 4. Phigh
- 5. Plow
- 6. Flow waveform

# Volume Support (VS)



Note! VS mode is a purchasable option.

VS mode is intended to be used on spontaneously breathing patients. During VS, the patient initiates spontaneous breaths and determines respiratory rate and timing. The ventilator maintains a PEEP level and provides support to deliver the set tidal volume (VT). For each breath, the ventilator adjusts the inspiratory pressure to use the lowest pressure required to deliver the tidal volume.

To determine the patient's lung compliance, the ventilator delivers volume-controlled ventilation for 10 seconds or two inspiratory periods, whichever is longer when the mode is initiated. Based on the patient's lung compliance, the inspiratory pressure is established and used for subsequent breaths.

The ventilator uses the following pressure range when adjusting inspiratory pressure:

- Low limit: PEEP + Pmin
- High limit: Pmax 5 cmH<sub>2</sub>O

The difference in inspiratory pressure between breaths does not exceed  $\pm 3$  cmH<sub>2</sub>O.

When the Minimum Rate is set during VS, the ventilator will deliver a mechanical breath if the patient's spontaneous respiratory rate is less than the Minimum Rate. The mechanical breath will be delivered at the Backup Pinsp pressure setting for the time duration of the Backup Tinsp setting.



**Note!** If a high airway pressure alarm is active for the current breath, the next breath's pressure target is  $0.5 \text{ cmH}_2O$  lower.

**Note!** Backup ventilation is available in VS mode. To set a Backup Mode, select **Current Mode > Mode Settings** and select **Backup Mode**.

Note! Tube Comp, Leak Comp, and Trigger Comp may be set if desired.

#### The following settings are available in VS mode:

Category	Settings
Main Parameters	FiO2
	VT
	PEEP
Patient Synchrony	Tsupp
	Insp Trigger
	Exp Trigger
	Bias Flow
	Rise Time
Safety	Pmax
	Pmin
	Minimum Rate
	Backup Tinsp

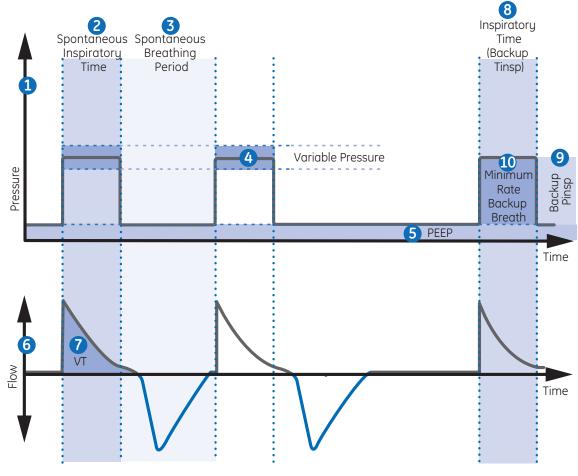


Figure 6.12 VS Waveforms

- 1. Airway pressure (Paw) waveform
- 2. Spontaneous inspiratory time
- 3. Spontaneous breathing period
- 4. Variable pressure
- 5. PEEP
- 6. Flow waveform
- 7. Tidal Volume (VT)
- 8. Inspiratory time (Backup Tinsp)
- 9. Backup Pinsp
- **10.** Minimum rate backup breath

# Non-invasive Ventilation (NIV)



**Note!** NIV mode is a purchasable option. NIV mode is intended to be used on spontaneously breathing patients.

During NIV mode, the patient draws spontaneous breaths as the ventilator maintains the set PEEP level and provides pressure support (PS).

Because flow triggers are affected by patient circuit leaks, flow and pressure triggers are applied simultaneously in NIV mode. When a flow trigger is set by the user, the ventilator uses a simultaneous pressure trigger to improve trigger detection.

The MVexp low, Apnea Time, and Leak Limit alarms may be disabled to prevent nuisance alarms when large patient circuit leaks are present. A medium priority alarm is active when any of these alarms is disabled. Select Audio Pause to acknowledge and de-escalate this alarm.

**WARNING!** If the Apnea Time, Leak Limit, or MVexp low alarms are disabled, additional monitoring, such as SpO<sub>2</sub>, ECG, and CO<sub>2</sub>, is recommended to prevent the patient from hypoventilating.

WARNING! If the patient does not meet the set Minimum Rate for spontaneous breaths, the ventilator delivers a backup breath based on the Backup Tinsp and Backup Pinsp settings. If the ventilator does not detect any spontaneous breaths within the set Patient Effort time, a high priority alarm indicates that the patient has stopped triggering breaths.

• While in non-invasive ventilation, the ventilator is to be provided with CO2 monitoring equipment that complies with ISO 80601-2-55 or ISO 21647. If the Apnea Time, Leak Limit, or MVexp low alarms are set to Off, additional monitoring such as  $SpO_2$  or ECG is also recommended to protect the patient from hypoventilation.



Note! Leak Comp and Trigger Comp may be set if desired.

Category	Settings
Main Parameters	FiO2
	PEEP
	PS
Patient Synchrony	Tsupp
	Insp Trigger
	Exp Trigger
	Bias Flow
	Rise Time
Safety	Pmax
	Backup Tinsp
	Minimum Rate
	Backup Tinsp

### The following settings are available in NIV mode:

**WARNING!** Before using NIV mode, the patient should demonstrate all of the following characteristics:

- Is responsive
- Breathes spontaneously
- Has a controlled airway
- Requires pressure support ventilation

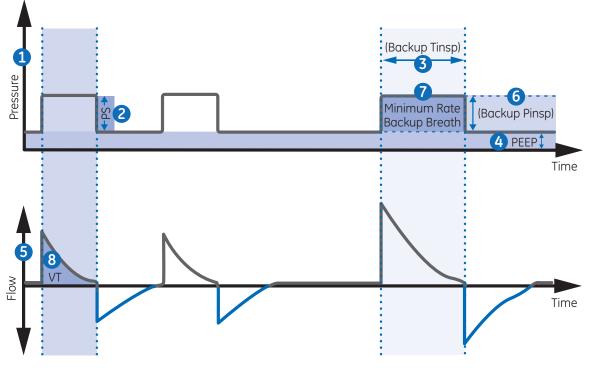


Figure 6.13 NIV Waveforms

- 1. Airway pressure (Paw) waveform
- 2. Pressure support (PS)
- 3. Inspiratory time (Backup Tinsp)
- 4. PEEP
- 5. Flow waveform
- 6. Backup Pinsp
- 7. Minimum rate backup breath
- 8. Tidal Volume (VT)

## Spontaneous Breathing Trial (SBT mode)

SBT mode is intended to be used to evaluate the patient's ability to breathe spontaneously during a specified duration of time. See **SBT view** in the **Clinical decision support** section.

Prior to the SBT evaluation, the following setting limits must be entered:

- SBT Duration
- Apnea Time
- High and low MVexp alarm
- High and low RR alarm

During SBT mode, the patient initiates spontaneous breaths as the ventilator maintains the set PEEP level and provides pressure support (PS).

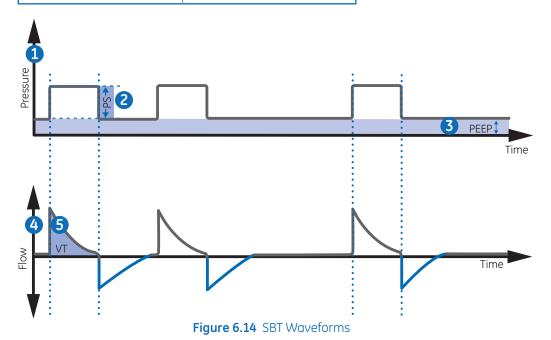


**Note!** To set a pressure support level for spontaneous breaths, select **Current Mode > Mode Settings** and enter a PS value.

**Note!** To evaluate the Spontaneous Breathing Trial, select **Clinical Decision Support** > **SBT.** 

Category	Settings
Main Parameters	FiO2
	PEEP
	PS
	Insp Trigger
	Exp Trigger
	Bias Flow
	PS Rise Time
Safety	Pmax
Stop Criteria	RR
	MVexp
	Apnea Time

- 1. Airway pressure (Paw) waveform
- 2. Pressure support (PS)
- 3. PEEP
- 4. Flow waveform
- 5. Tidal Volume (VT)



# 7 Procedures



# **Procedures Objectives**

### After completing this section, the participant will be able to:

- Utilize the Suction procedure
- Preform a Nebulizer Treatment and compensate for the additional flow
- Perform an Increase O<sub>2</sub> Procedure
- Perform an Inspiratory Hold
- Perform an Expiratory Hold
- Perform a Manual Breath Procedure
- Measure P 0.1
- Measure Negative Inspiratory Force (NIF)
- Measure Vital capacity
- Measure Auto PEEP and calculate PEEPi Volume

# Suction

Any ventilation modes and settings may be used with a closed suction catheter. Patient Disconnected, RR low, MVexp low, VTexp low, Apnea, and other alarms may occur during use of a closed suction catheter. To perform suctioning without nuisance alarms, an open suction procedure is provided by the ventilator.

The Suction procedure has three phases:

**Phase 1 Suction Oxygenation:** The ventilator delivers increased oxygen for two minutes or until the patient is disconnected.

**Phase 2 Suction Standby:** The ventilator enters Suction Standby for two minutes or until the patient is reconnected.

**Phase 3 Oxygenation:** The ventilator resumes ventilating at the current settings, delivering the increased oxygen value for two minutes.

CAUTION: If the current set value is  $1 \text{ cmH}_2\text{O}$  or less, PEEP or Plow will be increased to a minimum value of  $1.5 \text{ cmH}_2\text{O}$  to better detect a patient disconnect condition during the Suction procedure.



Figure 7.1 Suction Menu

- Select as a Favorite see Setting Favorites in the Operation section or select Menu > Suction.
- 2. Select *Start*. The Suction oxygenation, Suction, and Oxygenation general messages show as each phase occurs.
- **3.** Wait for the pre-oxygenation phase and then disconnect the patient at the wye. An audible tone sounds to indicate the patient is disconnected and ventilation is paused.
- 4. Suction the patient.
- 5. Reconnect the patient to resume ventilation.

The Suction procedure will end after the oxygenation phase completes, if Stop is selected, or if the Suction Favorite is selected.

### Nebulizer Treatment

The Aerogen® Professional Nebulizer System is a portable medical device that is intended to aerosolize physician-prescribed solutions and suspensions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The ventilator supports the Aerogen Pro and Aerogen Solo (disposable) in-line nebulizers. The nebulizer time can be set for specific duration delivery times or for the volume of medication that will be delivered to the patient. A general message shows the nebulizer treatment time remaining.

When the nebulizer is in use, gas sampling and monitoring from the airway module is suspended. The addition of nebulizer flow is not included in the  $FiO_2$  reading.

CAUTION: Only the Aerogen Solo (disposable) may be used for continuous delivery of nebulized medication.

Time (min)	7	8	11	16	21	26	32
Volume (ml)	2.5	3.0	4.0	6.0	8.0	10.0	12.0



Figure 7.2 Aerogen Nebulizer Menu

- 1. Select Menu > Nebulizer > Aerogen.
- 2. Select Time or Continuous.

Selecting **Continuous** will deliver nebulized medication until medication delivery is stopped or runs out.

The time and approximate volume of nebulized medication are shown in the table. This calculated volume is based on an average nebulization rate of 0.38 ml/min, but the actual nebulization rate of each individual nebulizer cannot be guaranteed and may vary significantly.

3. Select Start.



Note! To end a nebulizertreatment before the set time, select Stop.

## Pneumatic Nebulizer

The ventilator can compensate for additional flow introduced by a pneumatic nebulizer into the patient circuit. The displayed FiO<sub>2</sub> measurement does not reflect the additional gas introduced to the patient through the nebulizer.

# WARNING! Use of an external pneumatic nebulizer may significantly modify the mixture of gas that is delivered to the patient.

- Use of external pneumatic nebulization may significantly impact volume delivery and monitoring, decrease trigger sensitivity, and cause alarms if external flow is introduced and Pneumatic Nebulizer Flow Compensation is not used.
- When the Pneumatic Nebulizer Flow Compensation is On, flow and volume accuracy may be decreased.
- Leaks and flow sensor alarms may not be identified by the ventilator when Pneumatic Nebulizer Flow Compensation is On.

Menu		
System	Nebulizer	
Procedures	Aerogen	
Lung Mechanics	Pneumatic Vmin	
Nebulizer		
Suction		
		×

Figure 7.3 Pneumatic Nebulizer Menu

- 1. Select Menu > Nebulizer > Pneumatic.
- 2. Select the *Flow* value.
  - Set the flow value to match the amount of flow that will be introduced into the circuit. Flow setting is patient type dependent: 1.0 to 4.0 l/min for neonatal; 1.0 -12.0 l/min for adult and pediatric.
- 3. Select *Start*. A general message shows when nebulizer flow compensation is on.
- 4. Introduce the pneumatic nebulizer into the patient circuit.
  - For best results, introduce the pneumatic nebulizer into the patient circuit within approximately 15 seconds after selecting Start.



**Note!** To end a nebulizer treatment, turn the pneumatic nebulizer flow source off, then select **Stop**.

### Performing an Increase O<sub>2</sub> Procedure

Increase  $O_2$  is used to increase the amount of oxygen delivered to the patient to prevent low oxygen saturation levels.



Figure 7.4 Increase O<sub>2</sub> Procedure

- Select as a *Favorite* (the procedure will start immediately see *Setting Favorites* in the Operation section), or select *Menu > Procedures > Increase O<sub>2</sub>*, or press the *Increase O<sub>2</sub>* hard key.
- 2. Use the facility set increase  $O_2$ % or adjust the  $O_2$ % to the desired concentration and confirm the setting.
- 3. Select Start.
  - The oxygenation general message shows along with the progress bar and a 2 minute countdown timer. The progress bar fills in proportion to the amount of time the Increase  $O_2$  procedure has completed.
  - The procedure will end when the time has elapsed or when Stop is selected, or when the Increase O<sub>2</sub> Favorite is selected, or when the Increase O<sub>2</sub> hard key is pressed.

## Performing an Inspiratory Hold

The *Inspiratory Hold* procedure may be used during an x-ray procedure or to determine plateau pressure and static compliance calculations. When Inspiratory Hold is selected the inspiratory and expiratory valves close at the end of the next inspiratory phase. The Inspiratory Hold cannot be repeated until the patient triggers a spontaneous breath or the ventilator delivers a mandatory breath. Inspiratory Hold is not available in non-invasive ventilation modes.



Figure 7.5 Inspiratory Hold Menu

- Select as a *Favorite* (the procedure will start immediately) see *Setting Favorites* in the Operation section or select *Menu >Procedures >Inspiratory Hold*.
- 2. Select the Inspiratory Hold Time.
  - Use the Trim Knob to select an *Inspiratory Hold* time: 2 to 40 seconds for adult, 2-15 seconds for pediatric and neonatal.
- 3. Select Start.
  - A general message shows while the inspiratory hold is in progress.
  - The procedure will end when the *Hold Time* has elapsed or when *Stop* is selected.
  - Pplat and Cstat results will display along with a timestamp. If the measurement is not available, a red **X** will display indicating a failure.

## Performing an Expiratory Hold

The *Expiratory Hold* procedure is used to measure the end breath lung pressure. When Expiratory Hold is selected, the inspiratory and expiratory valves close at the end of the next expiratory phase. The expiratory hold cannot be repeated until the patient triggers a spontaneous breath or the ventilator delivers a mandatory breath. Expiratory Hold is not available in non-invasive ventilation modes.



Figure 7.6 Expiratory Hold Procedure

- Select as a *Favorite* (the procedure will start immediately) see *Setting Favorites* in the Operation section or select *Menu >Procedures > Expiratory Hold*.
- 2. Select the *Expiratory Hold* time.
  - Use the Trim Knob to select an Expiratory Hold time between 2 to 60 seconds for adult, 2-20 seconds for pediatric and neonatal.
- 3. Select Start.
  - A general message shows while the expiratory hold is in progress.
  - The procedure will end when the *Hold Time* has elapsed or when *Stop* is selected.

## Manual Breath

The Manual Breath procedure allows the clinician to deliver additional mechanical breaths to the patient. The ventilator requires a 0.25 second pause between delivery of breaths. The breath delivered is based on the settings for the current mode or backup ventilation mode if a rate is not set for the current mode. Manual Breath is not available in non-invasive ventilation modes.

Select as a Favorite (the procedure will start immediately) - see *Setting Favorites* in the Operation section or select *Menu > Procedures > Manual Breath > Add Breath*.



Figure 7.7 Manual Breath Procedure

## Measuring P 0.1

P 0.1 is a respiratory measurement used to evaluate the patient's readiness to be weaned from the ventilator. P 0.1 is a measurement of the airway occlusion pressure 0.1 second after beginning an inspiratory effort against an occluded airway.

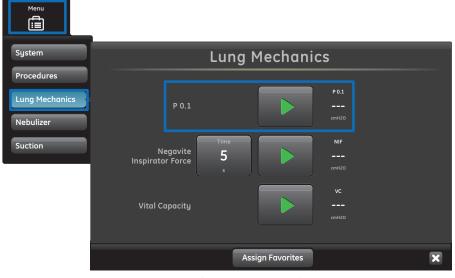


Figure 7.8 Measuring P 0.1

- Select as a Favorite. See Setting Favorites in the Operation section or select Menu > Lung Mechanics > P 0.1.
- 2. Select Start.
  - The P 0.1 measurement will display along with a timestamp.
  - The P 0.1 procedure will end when the measurement is completed or when **Stop** is selected. If the measurement is not available, a red **X** will display indicating a failure.

## Measuring Negative Inspiratory Force (NIF)

Negative Inspiratory Force is a weaning measurement that is used to evaluate the patient's readiness to be weaned from the ventilator. NIF is used to determine the patient's ability to take a deep breath and to generate a cough strong enough to clear secretions.



#### WARNING! The patient will not be ventilated during a NIF procedure.

Figure 7.9 Measuring NIF

- Select as a Favorite see Setting Favorites in the Operation section or select Menu > Lung Mechanics > NIF.
- 2. Set NIF Time.
  - Use the Trim Knob to select a NIF time up to 30 seconds.
- 3. Instruct the patient to fully exhale.
- 4. Select *Start* and instruct the patient to fully inhale.
  - When the patient inhales the most negative airway pressure is recorded and displayed along with a timestamp.
  - The procedure will end when the measurement is completed or when **Stop** is selected. If the measurement is not available, a red **X** will display indicating a failure.

## Measuring Vital Capacity

Vital Capacity is the measurement of a patient's largest (VTexp) expired Tidal Volume over a 30 second period.

During a Vital Capacity measurement, Pinsp and PS are set to zero. When the Vital Capacity measurement is complete Pinsp and PS return to the previous setting.

During the Vital Capacity procedure, VTinsp and VTexp for each breath will display in the Splitscreen view.

When the Vital Capacity procedure is complete, the largest VTexp value is displayed with a timestamp in the Lung Mechanics window.

**WARNING!** The patient will not be mechanically ventilated during a Vital Capacity procedure.



Figure 7.10 VC Menu

- Select as a Favorite see Setting Favorites in the Operation section or select Menu > Lung Mechanics > VC.
- 2. Select Start.
- 3. Instruct the patient to fully inhale and exhale.
  - The procedure will end when the measurement is completed or when **Stop** is selected. If the measurement is not available, a red **X** will display indicating a failure.

## Measuring Auto PEEP

Auto PEEP or Intrinsic PEEP is a measurement of pressure remaining in the lungs above the PEEP value at the end of a breath. It may be used as an indication of a patient's inability to completely exhale.



Figure 7.11 Auto PEEP Menu

- Select as a Favorite see Setting Favorites in the Operation section or select Menu > Procedures > Auto PEEP.
- 2. Select Start.
  - The ventilator measures Auto PEEP at the end of each controlled breath during a 30 second time period. Ifunsuccessful, the measurement procedure is cancelled.
  - Spontaneous patient breath triggers or activation of other procedures may cause an unsuccessful measurement.
  - The effects of breathing circuit compliance are accounted for in the Auto PEEP measurement.
  - The procedure will end when the measurement is completed or when **Stop** is selected. If the measurement is not available, a red **X** will display indicating a failure.

#### **PEEPi Volume**

Selecting **Auto PEEP** also calculates the PEEPi Volume. This is the approximate volume of air trapped in the lungs at the time the Auto PEEP procedure is started. PEEPi Volume is calculated from the current lung compliance and PEEPi measurement.

If PEEPi Volume cannot be calculated when Auto PEEP is selected,--- is displayed.

# 8 Patient Monitoring



## Patient Monitoring Objectives

#### After completing this section, the participant will be able to:

- Adjust the following Waveform Settings:
  - Waveform Configuration
  - Waveform Style
  - Waveform Speed
  - Waveform Color
  - Waveform and Spirometry Loop Scaling
- Configure Spirometry loops
- Configure the Splitscreen view
- Access one of the four trends views
- Utilize the Trends Timeline cursor
- Access the Graphical trends view
- Access the Numerical trends view
- Access the Alarm trends data
- Create a snapshot
- View snapshot data on the Mode view tab
- View snapshot data on the Measured view tab
- View snapshot data on the Waveforms view tab
- View snapshot data on the alarms view tab

## Waveform Settings

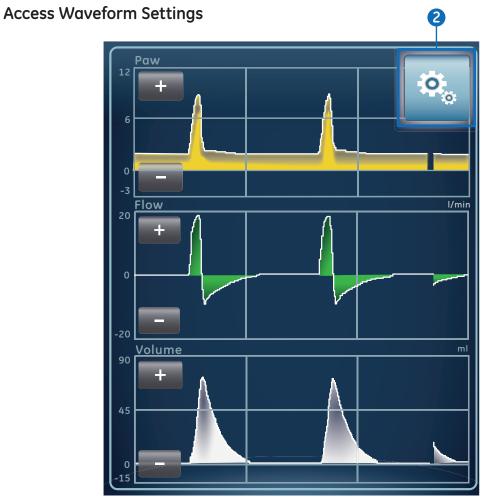


Figure 8.1 Select the settings icon to access waveform settings

- **1.** Select the waveform or spirometry loop. The settings menu displays with the **Settings** icon in the upper right-hand corner.
- 2. Select the *Settings* icon.
- **3.** Configure or adjust the desired settings.

#### Waveform Configuration

On the Waveform Settings menu, Basic Waveforms, Advanced Waveforms, and Splitscreen views can be customized to show up to four waveforms with measured data specified in the table below.

Wave Field	Options	Menu Adult No Alarms Alarm Setup
Fields 1 and 2	Paw	Waveform Settings
	Volume	
	Flow	Wave Field 1 Paw Orff Paw Wave Field 2 Flow Paw Flow
	Paux	Wave Field 3 Volume Volume Volume
Fields 3 and 4	Off	Wave Field 4 Off Flow Off Off 20
	Paw	Style Solid CO2 Fast PEEP
	Volume	Paw Flow Vol 02 1ux CO2 O2
	Flow	Color Vites Fi2 Scoling Auto Auto Auto Auto Auto
	Paux	
	CO <sub>2</sub>	on
	02	Current Mode         FI02         VT         Rote         LE         PEEP         Pinos           A/C VC         40         425         14         1:2         5         35         STANDBY           Mil         /min         /min         cmH20         cmH20         cmH20         H         H



**Note!** An airway module must be installed and set as the data source to monitor  $CO_2$  or  $O_2$  in Wave Field 3 or 4. Figure 8.2 Waveform Settings

#### Waveform Style

On the Waveform Settings menu, waveforms can be set as one of the following styles:

- Solid: the waveform curve or loop is filled with the set color.
- Outline: the waveform curve or loop is shown as a line in the set color.

#### Waveform Speed

On the Waveform Settings menu, waveform curves and loops can be set to Fast or Slow. The Fast setting travels at twice the speed of Slow.

#### Waveform Color

On the Waveform Settings menu, measured data can be set to show as one of the following colors:

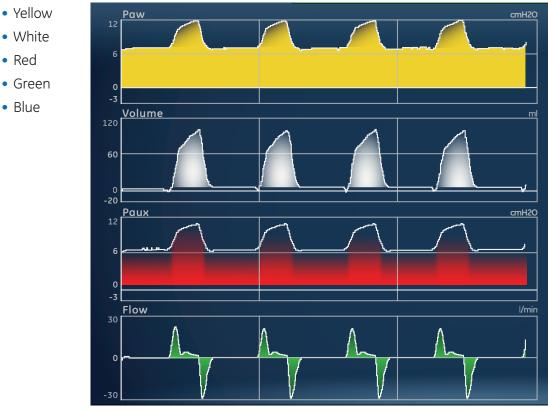


Figure 8.3 Waveform Colors

#### Waveform and Spirometry Loop Scaling

The range of values shown for each waveform can be set automatically or manually.

- Auto: The system scales the waveform to include the full range of the waveform curves or loop. The system continuously adjusts the scale as data is collected.
- Manual: Adjust the scaling controls to increase or decrease the scale of the waveform.

Manual adjustments to waveform scaling can be made when scaling is set to Auto. When a manual adjustment is made, the scaling setting changes to Manual.

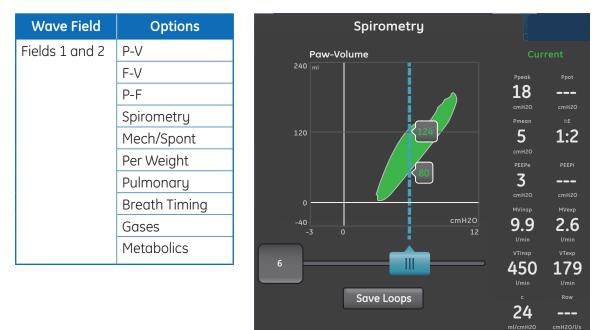


**Note!** Paw, Flow, and Volume scaling settings are available in both the Waveform Settings and Spirometry Settings menus. When set in either menu, they apply to both waveforms and spirometry loops.

## Spirometry Settings

#### **Configure Spirometry Loops**

On the Spirometry Settings menu, the Splitscreen view can be customized to display up to two spirometry loops or sets of measured data with data specified in the following table.





#### **Configure Splitscreen View**

On the Spirometry Settings menu, the Splitscreen view can be customized to display a spirometry loop or sets of measured data with data specified in the following table.

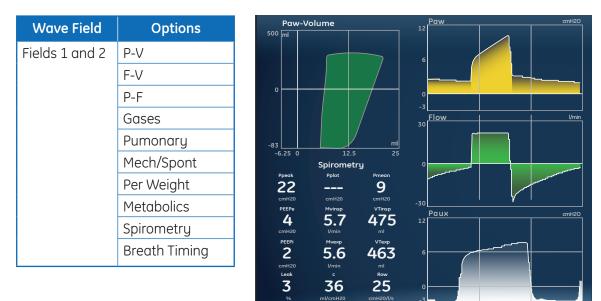


Figure 8.5 Split Screen View

## Trends Workspace

Use the Trends workspace to view patient data trends. The following trends views are available:

- Graphical trends
- Numerical trends
- Trend log
- Snapshot trends



Figure 8.6 Graphical Trends View

- 1. Trends timeline: Shows the past 72 hours of data. See *Trends timeline* for more information.
- 2. Guide setting: When set, shows MVexp, RR, Ppeak data, or EtCO2 (adult/ped) plotted on the timeline.
- **3. Timeline cursor:** Highlights the set period on the timeline. The timeline cursor range can be set to highlight 15 minutes, 30 minutes, 45 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, or 8 hours.
- **4. Trends list:** Shows data based on the selected trends view. The trends list shows the period of trending data highlighted by the timeline cursor.
- 5. Trends list cursor: Can be moved throughout the period shown to specific data points.

#### **Review Trends**

- 1. Access one of the trends views.
  - Graphical trends
  - Numerical (Measured data) trends
  - Trends log
  - Snapshot trends
- 2. Set a time period on the trends timeline cursor.
- 3. Position the timeline cursor to highlight the time period to show on the trends list.
- 4. Move the trends list cursor to review the data at specific points in time.

#### **Trends Timeline**

In the Graphical, Numerical, and Trends log views, the trends timeline shows the past 72 hours of data. The Guide setting plots data points on the timeline for one of the following data sets when available and selected:

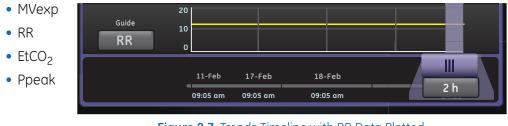


Figure 8.7 Trends Timeline with RR Data Plotted

The timeline cursor can be set to highlight 15 minutes, 30 minutes, 45 minutes, 1 hour, 1.5 hours, 2 hours, 4 hours, 6 hours, or 8 hours. The period highlighted on the timeline is the period shown in the trends list.

When alarms have occurred during the period shown on the timeline, the alarm priority color is displayed for the duration of the alarm.

- Data curves are colored red for the duration of active high priority alarms.
- Data curves are colored yellow for the duration of medium priority alarms.
- If medium and high priority alarms overlap, the data curve is colored red for the duration of the overlap

#### **Graphical Trends View**

The Graphical trends view shows plotted data for the period selected on the timeline. A dashed line extends from the cursor and intersects the data plotted on the Graphical trends view and Snapshot trends view > Waveforms tab. At the points of intersection, data values are shown. If an alarm is active at the point of intersection, the data value is colored for the alarm priority. Move the trends list cursor to the desired time on the plotted data shown in the trends list. Scroll through the trends list to view the data plotted in the Graphical trends view.

#### **Numerical Trends View**

The Numerical trends view has three tabs: the Mode tab, Measured tab, and Alarms tab.

- The Mode tab shows ventilation mode settings.
- The *Measured* tab shows measured patient data measured by the ventilator or airway module.



• The **Alarms** tab shows alarm settings.

Figure 8.8 Numerical Trends with Measured Tab

Move the trends list cursor to view measured data or ventilation mode or alarm settings at the desired point in time. Use the Measured tab and Mode tab to compare the measured data to the ventilator settings.

#### **Alarm Settings Trends**

The *Alarms* tab shows the alarm trends data for the following parameters:

- Apnea Time
- Patient Effort
- Tdisconnect

#### **Snapshot Trends View**

The Snapshot trends view shows a collection of data saved at selected times within the past 72 hours. Up to ten snapshots can be saved. When more than ten snapshots are saved, the oldest snapshot is deleted. A general message shows when a snapshot is deleted.



**Note!** To create a snapshot, press the Snapshot hard key on the Display Unit. The data is saved and can be reviewed on the Snapshot trends view.

A general message shows when a snapshot is created. Data is included in a snapshot and presented on the following tabs on the Snapshot trends view:

- Mode
- Measured
- Waveforms
- Alarms

In the Snapshot trends view, the trends timeline shows blue vertical lines to represent snapshots. Press the left or right arrow to navigate between snapshots.

#### **Mode Snapshots**

The *Mode* tab shows ventilation mode settings that were set when the snapshot was saved. Measured patient data snapshots

The Measured tab shows measured patient data that was available when the snapshot was saved.

Menu	Ac Q L	<sup>dult</sup> }ີ່ມີ ໄ	No Ala	rms			Alarm Set	tup Auto PEEP	P 0.1 Vital Compac	Manual ty Breath
							06-June-2015	15:47:43	Pa	
29-0ct :							01-No		60 <b>Cm</b> H	
Z9-Oct		M	easured		Waveforn		Aları			
MO	ue	M	eusureu		wavelorn	15	Aluli	lis		
Main Param	eters			A/C PC				]	40	
FiO2	VT	Pinsp	Phigh	Plow	Flow	PEEP	PS			
65		10				Off				
		cmH20	cmH2O	cmH2O	l/min	cmH2O	cmH2O			
Breath Timir	ng								20	Ppeak
Rate		Tinsp	Thigh	TFlow	Insp Pause	Tpause			20	
10		1.7								
/min										PEEP
Patient Sync	chrony								0	
Bias Flow	Rise Time	PS Rise Time	Tsupp	Insp Trigger	Exp Trigger				Ŭ	
3.0	100			2.0						
l/min				l/min					VTexp	FiO2
									450	65
Safety								$\sim$	ml	
Tube Comp	ensation		$\frown$						.≻	
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Figure 8.9 Snapshot Trends with Mode Tab

#### Waveform Snapshots

On the *Waveforms* tab, Paw, Flow, Volume, Paux, CO<sub>2</sub>, and O<sub>2</sub> waveforms are shown if data was available when the snapshot was saved. Move the trends list cursor to show waveform data values.



Figure 8.10 Waveform Snapshot

When a snapshot is taken, the duration of the waveform is based on the set speed.

- If speed is set to Slow, 15 seconds of waveform data is shown.
- If speed is set to Fast, 30 seconds of waveform data is shown.

Waveforms are shown in the color and scale set in the Waveform Settings menu.

#### **Alarms Snapshots**

The *Alarms* tab shows any low, medium, or high priority alarms that were active when the snapshot was saved.

#### **Review Snapshot Trends**

- 1. Access Trends > Snapshot Trends.
- 2. On the snapshot timeline, select the snapshot to show on the trends list.
- 3. Access the following tabs to review snapshot data:
  - Mode
  - Measured
  - Waveforms
  - Alarms

# 9 Cleaning and Maintenance



## **Cleaning and Maintenance Objectives**

#### After completing this section, the participant will be able to:

- Access the Part Replacement schedule
- Describe the purpose of the Inspiratory Safety Guard
- Remove the Neonatal Flow Sensor
- Re-assemble the Pedi-lite(+) and D-lite(+) Sensors
- Remove the Expiratory Flow Sensor
- Remove the Exhalation Valve Assembly
- Describe the process for cleaning parts manually with the soaking method
- Describe the process for cleaning parts automatically with an automated washer
- Describe the process for sterilizing parts automatically with an autoclave machine
- Clean, disinfect and sterilize the Aerogen Pro Nebulizer

## Part Replacement Schedule

The table shows recommended part replacement intervals. Replace the part at the interval or number of cleaning cycles, whichever occurs first.

\*Visually inspect parts to determine if cleaning or replacement is needed. Look for deformation, cracks, or discoloration.

Component	Interval	Cleaning Cycles
Exhalation Valve Assembly	12 months	50
Exhalation Valve Diaphragm	12 months	50
Expiratory flow sensor	6 months	50
Neonatal flow sensor	6 months	25
Aerogen Pro Nebulizer and T-adapters	12 months	26
Cart-mounted water trap	*As needed	50
Water trap connector tubing (hytrel tubing)	*As needed	50
Display and ventilator fan filters	*As needed	*As needed
Compressor air inlet filter	*As needed	*As needed
D-lite sensor	*As needed	50
Pedi-lite sensor	*As needed	50
Inlet filter bowl	*As needed	*As needed

## Inspiratory Safety Guard

The inspiratory safety guard cannot be cleaned. It is used to prevent patient gas from contaminating the inspiratory gas path of the ventilator. The inspiratory safety guard does not have to be replaced between patients; it must be replaced when patient gas has passed through the safety valve. This can occur in the following situations:

- Excess or sustained pressure in the system, as indicated by the following alarm messages: Relief valve opened, Patient circuit occluded, Sustained airway pressure.
- Failure of the Air and O<sub>2</sub> supply gases while connected to the ventilator.
- When the ventilator is ventilating and an internal error message displays; see "Internal errors" in the "Alarms and troubleshooting" section of the user's reference manual for a detailed list of error messages.

## Disassemble for Processing

In this section are the instructions to take apart assemblies prior to cleaning.

#### **Neonatal Flow Sensor (NFS)**

#### To remove the neonatal flow sensor:

- 1. Disconnect the flow sensor from the patient circuit.
- 2. Disconnect the flow sensor from the flow sensor cable.
- 3. Disconnect the flow sensor cable from communications port 1 on the back of the vent.

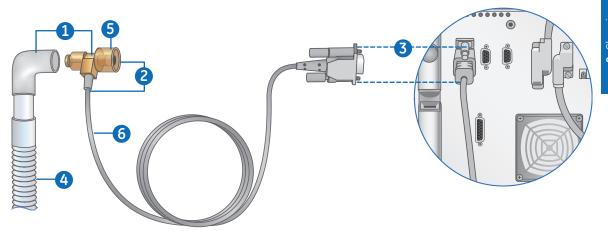


Figure 9.1 Disconnecting the NFS (Neonatal Flow Sensor)

#### Flow Sensor Components:

- 4. Patient circuit
- 5. Neonatal flow sensor
- 6. Flow sensor cable



**Note!** See the shared **Cleaning and maintenance** section of the user's reference manual for more information on cleaning. See **Calibrating the neonatal flow sensor** in **Neonatal Cleaning and Maintenance** in the user's reference manual for calibration information.

#### Pedi-lite(+) and D-lite(+) Sensors

See Connecting the Pedi-lite(+) and D-lite(+) sensors in Setup and connections in the user's reference manual.

Before re-assembling or using the Pedi-lite(+) or D-lite(+) sensor, do the following:

- Check for visible cracks, discoloration, or other degradation
- Check for leaks before use
- Replace any worn components
- Perform System Check

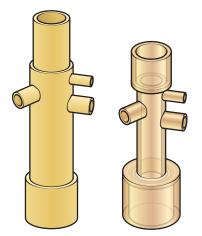


Figure 9.2 D-lite (+) and Pedi-lite(+)

#### **Expiratory Flow Sensor**

If the expiratory flow sensor is removed during ventilation, the ventilator will alarm, volume and flow measurements will not be shown, and flow triggering will not be available until the flow sensor is replaced.

#### Caution! Do not use an automated washer to clean or disinfect flow sensors.

- Do not use compressed air or a water jet to clean the expiratory flow sensor.
- Do not insert anything into the flow sensor to clean internal surfaces. Damage may occur to the flow sensor.

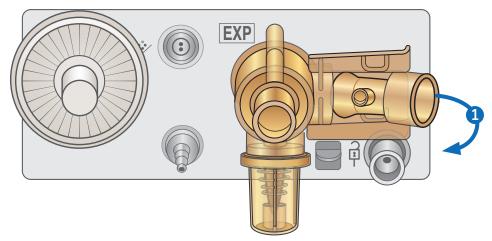


Figure 9.3 Removing the Expiratory Flow Sensor

#### To remove the expiratory flow sensor:

- 1. Pull the flow sensor away from the ventilator as shown.
- 2. Before re-assembling or using the expiratory flow sensor, do the following:
  - Check for visible cracks, leaks, discoloration, or other degradation
  - Replace any worn components
  - Perform a System Check



**Note!** Replace the sensor by positioning it back in place; listen for an audible click to ensure it is securely installed.

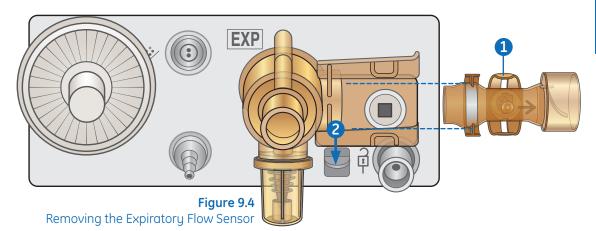
#### **Exhalation Valve Assembly**

Obey infection control and safety procedures when handling water traps. Infectious hazard might be present.

#### To remove the exhalation valve assembly:

- **1.** Make sure the expiratory flow sensor has been removed. If not, remove the expiratory flow sensor from the exhalation valve assembly.
- 2. Push down on the latch, as shown below, and then pull the exhalation valve assembly away from the ventilator.

Important! Do not try to remove the exhalation valve assembly without first pushing down on the release latch. Damage might occur to the housing.



- **3.** Remove the water trap and empty it. Make sure to save the o-ring from the water trap.
- **4.** Lift the edge of the diaphragm to remove it from the exhalation valve housing. Make sure to save the seal.
- 5. Before re-assembling or using the exhalation valve assembly, do the following:
  - Check for visible cracks, discoloration, or other degradation
  - Replace any worn components
  - Perform System Check



**Note!** *Re-assemble the exhalation flow sensor in reverse order.* 

#### **Exhalation Valve Components:**

- 6. Diaphragm
- 7. Seal
- 8. Exhalation valve housing (front view)
- 9. O-ring
- 10. Water trap

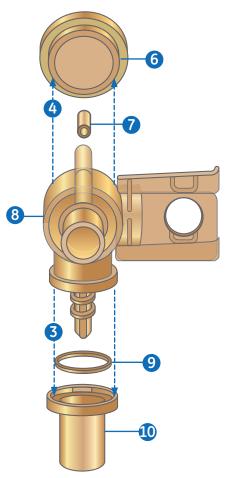


Figure 9.5 Exhalation Valve Components

## Manual Cleaning

#### Soaking

The following parts can be cleaned manually with the soaking method:

- Neonatal flow sensor
- Expiratory flow sensor
- Exhalation valve assembly
- Cart-mounted water trap and tubing
- D-lite sensor
- Pedi-lite sensor
- 1. Create a mild detergent solution by doing the following:
  - Dilute Neodisher Mediclean solution with warm potable tap water (less than 40° C) to form a 2% solution.
  - Create a homogenous solution by agitating the mixture.
- 2. Wash and soak the part(s) in the mild detergent solution for a minimum of 30 minutes in a clean soaking tray at temperatures up to a maximum of 40° C.
  - Ensure that all the surfaces of the part(s) are submerged and no air bubbles are visible.
  - Gently agitate the parts under solution to remove and dislodge any debris.
  - Use a soft, plastic brush to remove stubborn debris from external surfaces.

## CAUTION! Do not use a brush, abrasives, sharp tools or any methods that may damage the inside or surface of the parts.

- Submerge exhalation valve assembly or cart-mounted water trap in solution, and push down on the spring loaded plunger repeatedly.
- **3.** Rinse the part(s) thoroughly for two minutes in cold potable tap water (25° C); then rinse for two minutes with warm potable tap water (40° C).
  - Repeat steps 2 and 3 as necessary until parts are visually clean.
- 4. Remove the part(s) from solution allowing cavities to drain and dry in room air
  - Parts must be fully dry before disinfecting or re-assembling into the ventilator.
  - Do not wipe parts surfaces during the drying process.
- 5. Check the part(s) for deterioration such as deformation or cracking.

#### Hydrogen peroxide

It is recommended that the Sporox II solution be tested according to manufacturer instructions before use.

The following parts can be disinfected manually with the soaking method in hydrogen peroxide (Sporox II):

- Neonatal flow sensor
- Expiratory flow sensor
- Exhalation valve assembly
- D-lite sensor
- Pedi-lite sensor

- 1. Use the Soaking method to manually clean the part(s).
- 2. Soak the cleaned part(s) in Sporox II solution for a minimum of 30 minutes at 20° C in a clean soaking tray.
  - Ensure that all the surfaces of the part(s) are submerged and no air bubbles are visible.
  - Submerge exhalation valve assembly or cart-mounted water trap in solution, and push down on the spring loaded plunger repeatedly.
- **3.** Rinse the part(s) thoroughly for two minutes in cold potable tap water (25° C); flush all surfaces. Rinse all surfaces for two minutes with sterile or potable tap water (40° C); flush all surfaces. Finish rinsing with a 70% isopropyl solution to aid in drying.
- 4. Remove the part(s) from solution allowing cavities to drain and dry in room air.
  - Do not wipe the parts during the drying process.
- 5. Check the part(s) for deterioration such as deformation orcracking.

#### Ortho-phthaldehyde

It is recommended that the Cidex OPA solution be tested according to manufacturer's instructions before use.

The following parts can be disinfected manually with the soaking method in orthophthaldehyde solution (Cidex OPA):

- Neonatal flow sensor
- Expiratory flow sensor
- Exhalation valve assembly
- D-lite sensor
- Pedi-lite sensor
- 1. Use the Soaking method to manually clean the part(s).
- 2. Soak the cleaned part(s) in Cidex OPA solution for a minimum of 12 minutes at 20° C in a clean soaking tray.
  - Ensure that all the surfaces of the part(s) are submerged and no air bubbles are visible.
  - Submerge exhalation valve assembly or cart-mounted water trap in solution, and push down on the spring loaded plunger repeatedly.
- **3.** Thoroughly rinse the part(s) by completely immersing them in at least 2 gallons of sterile or potable water for a minimum of 1 minute. Finish rinsing using a 70% isopropyl alcohol solution.
- 4. Repeat step 3 two times.
- 5. Remove the part(s) from solution allowing cavities to drain and dry in room air.
  - Do not wipe the parts during the drying process.
- 6. Check the part(s) for deterioration such as deformation or cracking.

## Automated Cleaning

**WARNING!** Use only qualified and validated equipment for automatic cleaning and disinfection of components to ensure proper temperatures for disinfection are reached.

#### CAUTION! Do not use an automated washer with the neonatal flow

The following parts can be cleaned automatically with Prolystica Ultra Concentrate Neutral detergent (active ingredient(s): Disodium ethylhexliminod ipropionate, Triethanolamine, Sodium tolyltriazole).

- Exhalation valve assembly
- Cart-mounted water trap and tubing
- D-lite sensor
- Pedi-lite sensor
- Place the components in the washer tray and load into an automatic washer. Use Prolystica Ultra Concentrate Neutral Detergent as the cleaning agent, dispensed at 0.2 ml per liter of water.
- 2. Follow the automated washer operation procedure.
  - Prewash I with cold tap water; Set Hold time to 4 minutes.
  - Empty/drain water.
  - Prewash II with cold tap water; Set Hold time to 4 minutes.
  - Empty/drain water.
  - Clean with warm water for 4 minutes at 45° C.
  - Empty/drain water.
  - Rinse for 5 minutes.
  - Rinse an additional 5 minutes.
  - Set the thermal disinfection for 10 minutes at 90° C (A0=600 s).
  - Empty/drain water.
  - Dry for 25 minutes with hot air at 110° C. (If components are not dry after completion of the automatic washing program, they should be left to dry in open air).
- 3. After the completion of the wash cycle, unload the parts from the washer.
- 4. Allow the parts to cool in room air.
  - Do not wipe the parts during the drying process.
- **5.** After the parts have completely cooled and dried, check the parts for deterioration such as deformation or cracking.

## Sterilization

**WARNING!** Use only qualified and validated equipment for sterilization of components to ensure proper temperatures for sterilization are reached.

#### Autoclave

The following parts can be sterilized automatically with an autoclave machine:

- Neonatal flow sensor
- Expiratory flow sensor
- Exhalation valve assembly
- Cart-mounted water trap and tubing
- D-lite sensor
- Pedi-lite sensor
- 1. Use the manual Soaking method or the Automated method (as applicable) to clean the parts.
- 2. Place the parts in a legally marketed sterilization pouch.
- 3. Load the pouches into the autoclave machine.
- **4.** Follow the autoclave machine's instructions for use to program it with the following settings:

Temperature	Time	Dry Time		
132° C	4 minutes	20 minutes		
134° C	3 minutes	20 minutes		

- 5. After the completion of the sterilization cycle, unload the parts.
- 6. Allow the parts to cool in room air inside the sterilization pouch.
- 7. Store the parts in the sterilization pouch until they are ready to use.
- 8. Prior to use, check the parts for deterioration such as deformation or cracking.

## Aerogen Pro Nebulizer

The following cleaning, disinfection, and sterilization instructions are according to Aerogen, the manufacturer of the Aerogen Pro Nebulizer. Follow the manufacturer's instructions for processing.

#### **Component Replacement Schedule - Nebulizer**

Compon	ent	Minimum Frequency	Processing Cycles
Aerogen Pro nel T adapte		12 months	26

#### **Disassemble for Processing - Nebulizer**

Follow these instructions to disassemble the nebulizer before processing.

- 1. Remove the nebulizer from the T-adapter.
- 2. Firmly insert a plug into the T-adapter.
- 3. Disconnect the cable from the nebulizer.
- 4. Remove the filler cap from the nebulizer.
- 5. Before re-assembling or using the nebulizer, do the following:
  - Check for visible cracks, discoloration, or other degradation
  - Check for leaks before use
  - Replace any worn components
  - Perform System Check



**Note!** Follow the instruction for **Assembling the nebulize**r in Setup and connections in the user's reference manual to reassemble the nebulizer after reprocessing.

#### Nebulizer Components:

- 6. Filler cap
- 7. Nebulizer
- 8. T-adapter

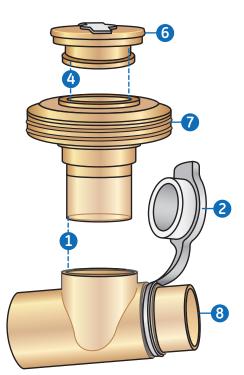


Figure 9.6 Disconnecting the NFS (Neonatal Flow Sensor)

#### Manual Cleaning - Nebulizer

This section includes cleaning of the nebulizer unit, T-pieces, and adapters.

#### CAUTION! Do not use abrasive or sharp tools to clean the nebulizer unit.

- 1. Make sure there is no medication remaining in the device.
- 2. Remove the nebulizer unit from the T-piece and then remove filler cap from the nebulizer unit.
- **3.** Clean all parts with warm potable water (40° C) and mild liquid detergent in accordance with current hospital protocols.
- 4. Rinse parts with sterile water.
- 5. Shake excess water from parts and allow parts to fully air dry.

### Manual disinfection - Nebulizer

This section includes cleaning of the nebulizer unit, T-pieces, and neonate adapters.

Aerogen approves the following disinfection solutions for use with its Aerogen Pro Nebulization System regarding material compatibility. With respect to microbiological effectiveness, please ask the manufacturer. Refer to the product labeling for specific instructions regarding activation, safe use, and disposal of these solutions.

- Isopropyl (70%)
- CIDEX
- NU-CIDEX
- CIDEX OPA
- Hexanios G+R

#### CAUTION! Do not use abrasive or sharp tools to clean the nebulizer unit.

- 1. Make sure there is no medication remaining in the device.
- 2. Remove the nebulizer unit from the T-piece and then remove filler cap from the nebulizer unit.
- **3.** Clean all parts with warm potable water (40°C) and mild liquid detergent in accordance with current hospital protocols.
- **4.** Completely immerse parts in appropriate disinfecting agent in accordance with current hospital protocols and disinfectant agent manufacturer guidelines.
- 5. Shake excess water from parts and allow parts to fully air dry.

#### **Automatic Cleaning and Disinfection**

The Aerogen Pro Nebulizer System has been validated with the Automated Washing Cycles One and Two.

**WARNING!** Use only qualified and validated equipment for sterilization of nebulizer components to ensure proper temperatures for sterilization are reached.

#### **Automated Cycle One**

- Detergent: Liquid alkaline cleaner (diluted according to manufacturer's instructions)
- Water quality: Mains water
- Method:
- 1. Load the components in the automated washer.
- 2. Pre-rinse the components for 3 minutes.
- 3. Clean the components with liquid alkaline cleaner at 55° C (131° F) for 10 minutes.
- 4. Rinse for 1 minute.
- 5. Rinse using thermal disinfection cycle at 93° C (199.4° F) for 10 minutes.

#### **Automated Cycle Two**

- Detergent: Cycle Two was validated without the use of detergent
- Water quality: Mains water
- Method:
- 1. Load the components in the automated washer.
- 2. Wash components at 91° C (195.8° F) for 10 minutes.
- 3. Drain the machine for 40 seconds.
- 4. Rinse at 90° C (194° F) for 1 minute.
- 5. Drain the machine for 40 seconds.
- 6. Rinse at 90° C (194° F) for 1 minute.
- 7. Drain the machine for 40 seconds.
- 8. Dry at 90° C (194° F) for 15 minutes.

#### **Sterilization - Nebulizer**

**WARNING!** Use only qualified and validated equipment for sterilization of nebulizer components to ensure proper temperatures for sterilization are reached.

- 1. Disassemble nebulizer and components.
- 2. Remove the filler cap from the nebulizer unit.
- **3.** Clean all parts with warm water (40° C) and mild liquid detergent in accordance with current hospital protocols. Rinse thoroughly and air dry.
- 4. Check for cracks or damage and replace if any defects are visible.
- 5. Place the disassembled components into appropriate sterilization wrapping.

#### CAUTION! Do not reassemble parts prior to autoclaving.

Sterilize components; Steam sterilization can be performed using the following three methods:

- I: Autoclave wrapped parts using steam sterilization prevacuum cycle, a minimum of 134° C (270-275° F) for 3.5 minutes with drying cycle (134° C wrapped cycle).
- II: Autoclave wrapped parts using steam sterilization prevacuum cycle, a minimum of 121° C (250° F) for 20 minutes with drying cycle (121° C wrapped cycle).
- III: Autoclave wrapped parts using steam sterilization prevacuum cycle, a minimum of 134° C (270° F) for 20 minutes with drying cycle (sometimes referred to as "Prion cycle").



**Note!** Sterilization using the long autoclave cycle (III above), may cause some ares of the nebulizer to become discolored. This is not indicative of the performance of the nebulizer unit. To sterilize with hydrogen peroxide gas plasma, place wrapped parts in STERRAD System and use the long cycle.

## CAUTION! Refer to the product labeling for the STERRAD 100S Sterilization System for specific instructions regarding its proper operation.

6. Store the parts in the sterilization wrapping until they are ready to use.



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